THE OUTCOMES OF CATARACT SURGERY : THE RELATIONSHIPS BETWEEN VISUAL ACUITY, VISUAL FUNCTION AND QUALITY OF LIFE

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ABSTRACT

This thesis has assessed the outcomes of cataract surgery not only in terms of clinical measures of impairment and but also using patient perceived measures of disability and handicap. The inter-relationships between these measures and the additional contributions that patient perceived measures can make to the assessment of cataract outcomes have been identified.

Two prospective cohort studies were conducted in which patients admitted for surgery for age related cataract were studied. The first of these described current surgical practice and clinical outcomes (visual acuity after surgery and complications) throughout the UK. Patients were followed up for three months and risk factors for poor clinical outcome were identified and quantified. Using Poisson logistic regression analysis, relative risks as measures of effect were calculated for this purpose.

The second cohort study was concerned with patients' perceptions of their visual function (disability) and quality of life (handicap), before surgery and at 4 and 12 months after. Visual function was assessed using the VF-14. The Sickness Impact Profile (SIP) was used to assess general quality of life, and its modification, the VR-SIP, was used as a vision-specific measure of quality of life. Measures of association (provided by multiple regression and analysis of covariance) were used to examine the relationships between the clinical measure of outcome (visual acuity) and the patient perceived measures. The influence of the sensory input from *both* eyes on these relationships was examined. Important confounders influencing the extent of change in patient perceived measures achieved after surgery were identified.

The findings have implications for clinical practice as regards timing of surgery to maximise benefit, and the additional contribution of second eye surgery. These are discussed together with the role of clinical and patient perceived measures for the assessment of the outcome of cataract surgery.

This thesis is dedicated to my son David.

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Chapter 1

BACKGROUND AND LITERATURE REVIEW

1. INTRODUCTION

A specific and systematic interest in the epidemiology of eye diseases - ophthalmic epidemiology - has probably only emerged in the last 15 years or so. In terms of research interest and methodology (in the widest sense of epidemiology and public health), it has received far less attention than cancer, heart disease, or communicable diseases. It has largely been concerned with aetiology - the study of the distributions and determinants of disease, particularly blinding eye disease. This initially started in the developing world and only more recently was extended to include the developed countries, notably the United States of America (USA) and the United Kingdom (UK). So far, these studies have used epidemiological methods to inform the planning and provision of eye health services by mapping the patterns of blinding disease and estimating the burden of these diseases in populations; and aetiological studies into risk factors for these diseases have aimed to inform their treatment, management and prevention.

At the time that this work was started, there had been little work on health services research in ophthalmology making use of epidemiological methods. Little attention had been paid to the services provided, the effectiveness and outcomes of interventions - both the treatment (or management) of disease and preventive measures. By the application of epidemiological methods information can be obtained on the characteristics and distribution of health care and the determinants of the outcome of this care i.e. outcome indicators and risk factors for poor outcomes. This can contribute to planning and providing eye health services so as to maximise the public health impact of interventions.

The application of epidemiological methods to the study of health care requires a wider perspective than that adopted in aetiological epidemiology. The latter has, to date, centred on clinical assessment and definition of disease, and for eye conditions the impact of disease on vision has been assessed in terms of its effect on visual acuity in the affected eye(s). This has resulted in a range of standard measurement methods ranging from fairly simple field methods to more sophisticated photographic and imaging techniques such as lens grading systems. [1][2][3] Whilst these may also be applied to the clinical assessment of outcomes of treatment, they are limited both to the impact of treatment on the affected eye and to its physiological and optical functioning (impairment). The impact of interventions should however, also consider the impact of disease and its management on patients functioning (ability) and well being (quality of life or handicap). These are less well defined concepts and raise methodological issues regarding measurement, interpretation, and how they may relate to clinical factors. The principal aim of treatment is to restore or maintain vision (with vision being measured by visual acuity). This is based on the assumption that this will influence functioning and quality of life. Cataract provides a suitable model for assessing these relationships :

- Both the severity of a cataract and its effect on vision (visual acuity) may be defined in terms of the degree of lens opacity present and its location within the lens. On removal of the cataractous lens an immediate effect is usually observed.

  In conditions where other modalities of vision are involved, visual acuity is not necessarily the best indicator of the impact on vision or even severity of disease. For example, patients with advanced glaucoma may have good visual acuity (6/6) but have very constricted fields and diabetic patients may have 6/6 vision but have severe sight threatening proliferative retinopathy. In such circumstances the relationships then become more complicated.

- Cataract is a common cause of treatable visual impairment and blindness.

- Cataract extraction is a high volume procedure and little is known about its outcome not only in current surgical practice, but also in terms of functional ability and quality of life.

This thesis is concerned with the application of epidemiological methods for the assessment and measurement of the outcomes of cataract surgery and in particular, the relationship between clinical outcome and patient perceived outcomes (visual functioning and health related quality of life) and their potential application in routine clinical practice.

Whilst it may be important to identify the earliest changes that represent onset of disease in aetiological epidemiological studies for cataract, or to identify cataracts that are severe enough to interfere with vision in prevalence surveys designed to estimate the burden of cataract in a population, such studies may identify cases of cataract amongst persons that are asymptomatic or unaware of their impairment. [4][5][6]. In contrast, this thesis has used an operational definition of cataract based on a need for surgery as judged by the patient's surgeon, for the patient with functional disability from cataract that has presented to the health care system.

2. CATARACT SURGERY

A cataract is an opacity of the otherwise transparent crystalline lens of the eye. The location and size of the opacity within the lens will determine the level of visual impairment. The term "cataract" in this thesis refers to a cataract that occurs in adults of 50 years of age or more, commonly known as age-related cataract. It does not include congenital and secondary cataracts which are specific entities with specific aetiologies and constitute a small proportion of all cataracts. Three main morphological types of cataract in adults are recognised : nuclear sclerosis, cortical and posterior subcapsular. No distinction between these types of cataract are made in this thesis.

2.1 The Epidemiology of Cataract

Cataract is widely distributed and is an important cause of visual impairment and blindness world-wide.[7] Estimates of the prevalence of cataract from cross-sectional surveys indicate a strong relationship with increasing age. Although differences in the definition of cataract used in these studies have not always made them directly comparable, all definitions usually use a level of impairment of Snellen visual acuity that is attributed to lens opacity. The Snellen visual acuity chart bears letters of diminishing size, so that when viewed from a specified distance, the eye must have a limit of resolution of one minute of a degree. The largest letters have a viewing distance of 60 metres, with smaller letters for distances of 36, 24,18,12, 9, 6 and 5 metres. The patient is usually positioned 6m from the chart. A visual acuity of 6/6 denotes optimal resolution of the eye, whilst an acuity less than that i.e. ranging from 6/9 to 6/60 and blindness, represent increasing levels of impairment.

Data from the Melton Mowbray Study estimated that the prevalence of some degree of cataract reducing visual acuity to 6/9 or less is about 42% in people 76-84 years of age and 65% in people 85 years and over. [8] The estimates for the 76-84 year age group are comparable to findings from the Framingham and Beaver Dam studies in North American

populations using the same definition for cataract.[9][10] The prevalence of lens opacities in younger age groups estimated from these American studies suggest that it is between 4.5% to 7% amongst persons of 52-64 years of age, and 18% in persons of 65 to 74 years of age. [9][10]

Direct age-specific estimates of incidence of *blinding* cataract have been obtained for India where increasing incidence has been convincingly demonstrated with increasing age. The oldest age group in the cohort (65 years and over) had an incidence rate of blinding cataract of 0.0581 per person-year and the youngest age group (35-39 years) had an incidence rate of 0.0019 per person-year.[11] Currently these type of data are not available for an industrialised country for cataract that is not only blinding but one that is visually impairing, but are the subject of ongoing investigations.

The cause of cataract is probably multifactorial. Apart from age, recent studies have identified a number of risk factors for cataract :

* nutrition and socio-economic status [12] [13] [14] [15] [16]
* dehydration/diarrhoeal crisis [17][18]
* ultra-violet light [19][20]
* life style - smoking, alcohol [21] [22][23][24][25]
* diabetes mellitus [26]

The relationship with age raises the question of whether cataract is a direct consequence of the ageing process or whether age is an indicator of the risk of being exposed to causes of cataract. Although the scientific evidence is not complete yet, indications are that improved sanitation and nutrition would remove some of the global burden of cataract.

2.2 Management of Cataract

Currently the only treatment to relieve visual impairment or blindness caused by age related cataract is surgical extraction of the lens. It is one of the oldest ophthalmic procedures - couching was first performed over 2000 years ago in India.[27] The objective of surgery is to restore or improve vision by removing the cataractous lens and providing some form of optical correction in replacement. For age-related cataract, in cases where both eyes are affected, the worst eye is usually offered surgery first.

2.2.1 The Surgical Procedure

Surgical techniques for cataract surgery have changed radically over the last twenty years or so as a result of the introduction of microsurgical techniques for extracapsular extraction and implantation of intraocular lenses.

Prior to this development the surgical procedure of choice was an intracapsular cataract extraction which was performed in over 90% of cases in the 1970s.[28] The lens and its capsule in its entirety were removed. This not only left the eye anatomically and optically deficient, but also altered the stability and dynamics of the anterior and posterior segments of the eye.[29]

The resulting aphakia (absence of the lens) required high powered (dioptric) convex lenses for optical correction, usually in the form of glasses, to focus light on the retina. Due to the physical properties of the lens, such high powered aphakic spectacle corrections are associated with optical aberrations.[30] In particular, these include image distortion and a ring scotoma which are most troublesome in the peripheral field viewed through the lens. This together with the magnification of the resulting image (33% relative spectacle magnification) seen through the corrective lens, compromises the quality of post-operative vision making these spectacles difficult for patients to tolerate. Contact lenses overcome some of these problems and were also used as an alternative to spectacles. [30]

In contrast, extracapsular methods of cataract extraction express the nucleus of the lens and remove the cortical matter by aspiration and irrigation techniques. The posterior capsule is left intact to allow for positioning of a posterior chamber lens implant.[29]

Intraocular lenses (anterior chamber) were first used in 1949 to correct the consequences of aphakia from cataract extraction [31], but their use was soon abandoned due to the nature of the complications that resulted.[32] Various types have been developed since then that fall into two main types : anterior chamber or posterior chamber lenses. The latter type is placed in the usual anatomical site of the natural lens and has subsequently become the preferred type of intraocular implant. By their location in the eye, intraocular lenses become an integral part of the optical system of the eye. Consequently they cause minimal magnification of the resulting image (0.1%), they are not associated with the problems of optical aberrations and are able to provide a superior optical quality of post-operative vision compared to aphakic spectacles.[30]

The combination of microsurgical extracapsular cataract extraction and intraocular lens implantation requires special instrumentation, materials and surgical training. By the mid 1980s, extracapsular cataract extraction and intraocular lens implantation accounted for about 50% of procedures.[33][34] Surgical practice at this time was clearly changing with respect to technique, and was associated with various types of anterior and posterior chamber intraocular lens implant in varying stages of design and development. Other technologies continued to be developed to further refine the method of extracting the lens in extracapsular surgery (e.g. phako-emulsification, in which the nucleus of the lens is fragmented by ultrasound and aspirated).

There has also been a gradual interest in the use of local anaesthesia for both types of procedure and more recently, the introduction of day-case surgery under local anaesthetic.[35][36] In other parts of the world this is almost routine[31] and it has been suggested that day case surgery will be a more cost-effective means of delivering a surgical service for such a high volume procedure.[38]

By the time that this thesis was started, it was possible that surgical practice and technical developments may have stabilised, but there was no evidence to support this assumption, and accurate and complete information on surgical practice was not available from routine sources.

2.2.2 Indications for Surgery

Cataract surgery is clinically indicated in the presence of a lens opacity when visual acuity has reached a stage where the patient is compromised in his or her daily activities. Requirements for good vision and the level of acuity at which it is compromised varies considerably between patients. The basic proviso has been that the benefits of surgery in restoring or improving vision should outweigh the risks associated with anaesthesia and the surgical procedure itself. There is a clinical consensus on these principles[37][39] which have only been adjusted in response to developments and advances in surgical techniques that have altered the risk : benefit ratio toward greater benefit or less risk.

However, for the vast majority of cataract patients in developing countries, surgery is often only available for blinding cataract. This is due to demand exceeding supply as result of a variety of factors which include amongst them an excess burden of cataract in some areas of the world, lack of resources, and poor access and availability of health services. In these situations those assessed as having greatest need are given priority, the blind getting priority over the visually impaired.[40][11]

Ideally, the threshold at which surgery is indicated would be given by the visual acuity at the time the decision for surgery is made. As this information is rarely if ever reported in the literature, visual acuity at the time of surgery, which is more widely reported, has been used instead. As practice changed from intracapsular surgery with spectacle or contact lens correction of aphakia in the 1970s to extracapsular cataract extraction with intraocular lens implantation in the mid 1980s with the potential of providing better optical correction and thus better quality of post-operative vision, the threshold of visual acuity at which surgery was performed fell from blindness or counting fingers to 6/60.[28][33[41][42] More recent thresholds have not been reported.

The optical aberrations associated with the aphakic correction after intracapsular surgery, made this type of surgery unsuitable for many patients. This included patients with monocular cataract with good vision in the fellow eye. The aniseikonia resulting from aphakic spectacle correction would not only be intolerable, but also proclude binocular vision in these patients.[30] Patients with significant ocular comorbidity compromising the central field of vision which is essential for using an aphakic correction (e.g. ageing maculopathy), were also unsuitable for surgery.[43][44] Whilst contact lenses overcame these problems and were an alternative to spectacles[30], they were not suitable for all patients.[44]

As intraocular lenses are not associated with these optical problems, their introduction made it possible to offer surgery to patients who would otherwise have been unsuitable for intracapsular surgery, and also to consider surgery at levels of vision other than blindness or counting fingers.[28][33][41][42]

2.3 Demand for Cataract Surgery

Cataract extraction for age related cataract is one of the commonest surgical procedures performed within the National Health Service (NHS) and consequently cataract poses a significant burden on ophthalmic surgical services. It accounts for a significant proportion of all new referrals to ophthalmic out-patient departments, and about a third of all ophthalmic procedures.[33][45] The number of operations performed has been steadily increasing. In England and Wales operations for cataract increased by almost two-thirds in the decade up to 1985.[46] A substantial proportion of patients (75%) on ophthalmic waiting lists for surgery are those waiting for cataract surgery.[47][48]

Improvements in surgical techniques and visual rehabilitation, notably extracapsular extraction with intraocular lenses, have resulted in falling thresholds[28][33][41][42] and changing indications of surgery[30][43][44] (including second eye surgery). This has

undoubtedly contributed to the increasing demand and, with the prospect of an increasingly ageing population, it is likely to continue to do so.

The demand as referred to above relates to a special group of patients who have recognised a visual problem themselves, presented to or been identified at the level of primary health care, and have had a diagnosis of cataract confirmed and treatment offered at secondary level care.

3. ASSESSMENT OF OUTCOMES

Measures of health have traditionally been based on the concept of the "disease model" (the presence or absence of disease), indicated by a set of signs and findings, providing an objective assessment of health outcomes in terms of mortality or morbidity. Whilst these may indicate ill-health, they fail to encompass other dimensions of health. A person's perceptions of change in usual functioning and well-being based on the concepts of "illness and ill-health", may also be important indicators of outcome. Although these are distinct concepts of health, they are not mutually exclusive. Those based on the former are referred to as clinical outcomes in this thesis and those based on the latter are referred to as patient perceived outcomes.

Patient perceived outcomes require a subjective assessment of health in that it is based on individuals' own reports. Initially measures for this type of assessment were uni-dimensional, focusing on physical functioning or mental health. This was followed by the development of multidimensional measures that address a wide range of functions, and well-being (or quality of life).

The theoretical model used in this thesis for the measurement of outcomes and assessment of the relationships between these different types of outcomes (clinical and patient-perceived), relates measures of outcome to impairment, disability and handicap

(Figure 1.1).[49] Impairment describes an anatomical or physiological defect. Disability describes the effect on an individual's physical or mental function, and handicap describes the extent to which the disability or impairment effects the individual's quality of life.

Figure 1.1 Model for the Assessment of Cataract Surgery

	CLINICAL MEASURES (Objective)	PATIENT PERCEIVED MEASURES (Subjective)	
DISEASE SPECIFIC	Visual Acuity Complications	Visual functioning e.g. VF-14 Symptom Severity Scores Global measures of vision	Modified generic measure e.g. Vision-Related SIP Symptom Bothersome Score
GENERIC	—	Functional component of a generic quality of life measure e.g. SIP Global measures of health	Measure of health related quality of life e.g. SIP
	IMPAIRMENT	DISABILITY (Functional Status or Health Status)	HANDICAP (Well Being or Health Related Quality of Life)

3.1 Clinical Measures

Clinical measures provide an assessment of impairment and the impact of interventions on the disease state. As such, the outcomes of medical or surgical interventions have traditionally been considered in terms of mortality and morbidity. Mortality (or survival) is not relevant in ophthalmology as most conditions are not life threatening.

Measures of morbidity include the results of a clinical evaluation, physiological or biological investigations, and the occurrence of complications. These are more relevant to the outcomes of ophthalmic interventions, including cataract surgery, than mortality. The main measures of morbidity are visual acuity and complications associated with the treatment.

3.2 Patient Perceived Measures

Patient perceived measures provide an assessment of the impact of the disease and the intervention(s) on daily life and functioning.

3.2.1 Functional Status

This is a component of health, measuring the effects of physical impairment on function. It can be used to assess outcome of care in a broader sense in terms of a person's ability to perform tasks of daily living. These may be more meaningful to people's lives than measures of impairment.

Most measures of function (or disability) require the respondents to report limitations on their activities. There are many measures of functional status. These include broad measures of function like the Index of Activities of Daily Living (ADL),[50][51][52] and more disease specific measures like symptom severity e.g. the Arthritis Impact Measurement Scale.[53] Symptom check lists are commonly used in studies of health

related quality of life.[54][55] Respondents are typically asked to indicate which, if any, they currently suffer from or are bothered by.

The limitations of these methods are that the may include response errors and diagnostic errors - many people are not aware of the specific nature or cause of their afflictions. Reporting of morbidity may also depend on tolerance levels and pain thresholds. The decision to restrict activities may reflect an individual's attitude to illness and self-care, the expectations and demands of others (family, friends), knowledge and understanding of symptoms experienced and other social and cultural factors.[56]

Most scales of this type have been developed on the basis of professional judgements about essential abilities for daily living. Lay judgements of essential functions were rarely included.[56] The areas most frequently addressed are self care, mobility and physical activity.

3.2.2 Health Related Quality of Life

This term is often (though incorrectly) used interchangeably with the term "health status" or "functional status". Health status refers to a level of health in terms of physical functioning, social functioning and mental health. Health related quality of life refers to the impact of health states on an individual's quality of life or well being. Different patients react differently to apparently similar levels of functional status or disability depending on their expectations, previous experience, priorities, and social and physical environment.[57] Indices of functional ability may distinguish between groups of people with different levels of ability, but do not take account of functioning in everyday social roles or the impact on emotional or social needs and well being of the patient i.e. are not concerned with quality of life.

Whilst there is no consensus over the definition of "health related quality of life",[56] it is accepted that physical, social and cognitive well being should all be included. The term is recognised as a concept representing individual responses to the physical,

mental and social effects of illness on daily living which influence the extent to which personal satisfaction with life circumstances can be achieved.[56][58][59]

Health related quality of life represents a subjective assessment of health which assumes that individuals experience illness in ways that cannot be measured well, yet may influence outcomes.[60][61] Instruments for measuring health related quality of life which have been developed attempt to measure well being in the physical, psychological and social domains of health. These are seen as distinct areas that are influenced by a person's perceptions of health determined by their experiences, beliefs, and expectations of health. Many, however, have been derived from professionals' conceptions of well being.[56] The Sickness Impact Profile[62][63][64] and the Nottingham Health Profile[65] however, are two instruments that have been derived from interviews with lay people.

Most instruments measure each domain separately by asking specific questions pertaining to its most important components. The responses are converted to numerical scores to provide a profile of scores for each domain. In some instruments component or category scores may be aggregated to yield overall index scores.

There is no "gold standard" for measuring health related quality of life, that may be used for the selection of an instrument, in assessing the performance of different instruments, or for assisting in the clinical interpretation of the scores or change in the scores produced by these instruments.[66]

3.2.3 Generic v. Disease Specific Instruments

Health related quality of life can be measured in two ways : by a generic measure or a disease-specific measure. Both generic and disease specific instruments have been developed with considerable attention to assessing their reliability, validity and more recently, their responsiveness to change. Both generic and disease specific instruments may be subject to ceiling and floor effects whereby patients who score at the extreme end of a questionnaire scale are unable to register any improvement (or deterioration) in later assessments.[67][68]

The generic instruments that have been developed have been designed to provide a general health profile and have been subjected to considerable psychometric testing for measurement properties (reliability, validity and responsiveness to change).[64][65][69][70][71][72] These have been designed to be used for assessing a wide range of domains applicable to a variety of health states, conditions and diseases. They permit comparisons of different populations and of the benefits of different health interventions. Generic measures used in condition or population specific situations may have low content validity because they contain items of little or no relevance to study participants, and may exclude certain particular concerns of study participants. This may also reduce their responsiveness to change . Also they may include items that assess areas that that are relatively static or not feasible targets of the intervention e.g. patterns of social relationships.[73]

Disease specific instruments have been developed to focus on domains most relevant to the disease or condition under investigation and on the characteristics of patients in whom the condition is most prevalent.[73][74][75] These instruments are useful for identifying important concerns of patients with particular conditions and for measuring small, clinically important changes from specific treatments. Disease specific measures have items selected to assess particular concerns of study participants and have high content validity for clinical investigations of special populations. They may be particularly sensitive to within person changes and be more responsive than generic measures that contain items unrelated to change

3.2.4 Global assessments of health

These are single item measures that usually ask respondents to rate their health as "excellent", "good", "fair" or "poor", and sometimes in relation to their age or peers, providing a global health rating. Strong associations have been demonstrated with worsening global scores and worsening scores from more complex multidimensional profiles.[76] Ratings from such questions correlate well with subsequent mortality and admission to hospital.[77] They have also been used to assess the criterion validity of multidimensional scales.[78][79][80]

3.3 Clinical Measures of Cataract Surgery

The outcome of cataract surgery has traditionally been considered in terms of the change in best corrected post-operative Snellen visual acuity in the eye that had surgery. Complications have also been considered, but usually in terms of the occurrence of an individual complication and its management.

3.3.1 Visual Acuity

Vision is made up of both optical and neural components. All types of cataract interfere with vision through their basic effect on the optical system of the eye, by causing light scattering.

Visual acuity is probably the single most significant measure of the functional integrity of the eye. It is routinely assessed in all patients with visual problems. Visual acuity refers to the limit of resolution or the resolving power of the eye i.e. the smallest angle of separation between two points which allows discernible images by an optical system. The normal limit of resolution (minimum angle of resolution) for the eye is one minute of a degree. Visual acuity provides a single measurement of visual performance at the limit of resolution for the combined effects of the ocular media and retina/brain at high contrast.

Visual acuity in a clinical setting is routinely measured by the Snellen Test Type - a high contrast acuity chart. This Snellen chart bears letters of diminishing size, so that when viewed from a specified distance, the eye must have a limit of resolution of one minute of a degree. The largest letters have a viewing distance of 60 metres, with smaller letters for distances of 36, 24,18,12, 9, 6 and 5 metres. The patient is usually positioned 6m from the chart. A normal eye reads the 6m letters from a distance of 6m and is said to have 6/6 vision. A weaker eye may only be able to resolve the larger letters e.g. the 36m size, and is said to have 6/36 vision. [30] Visual acuity is usually assessed unaided and best corrected (wearing glasses if worn, or with pin-hole or after refraction) for each eye, separately.

The design of the Snellen chart produces a variation in the ratio of letter size between successive lines; the separation of letters within and between lines; and the number of letters on each line. The resultant variation in contour interaction consequently requires a different visual task for letters of different angular size at each level of the chart. The effects of contour interaction are responsible for the main limitations of the Snellen chart for measuring very good and very poor levels of visual acuity.[81][82][83]

Other high contrast visual acuity charts have been developed to overcome these limitations of the Snellen chart e.g. Bailey-Lovie Letter Chart.[81] Such charts have an equal number of letters on each row, and the separation of letters within and between rows is uniform so that contour interaction is controlled. The visual task at each level of the chart is therefore the same irrespective of the acuity or test distance[81]. The chart employs a logarithmic progression of letter sizes and produces the logMAR visual acuity notation. The major advantage of the logMAR visual acuity notation and the use of this type of chart, especially for research purposes, is its ability to measure and score low visual acuities accurately, and consequently allows for them to be included and handled appropriately in statistical analyses. Whilst charts such as these have been used for research purposes in a variety of settings[84][85][86], they are not used in routine clinical settings.

The test-retest reliability of *uncorrected* Snellen visual acuity measured at one moment in time, is reported to be comparable to **uncorrected** visual acuity measured by the Bailey-Lovie chart ($r=0.94$ and $r=0.98$, respectively).[87] These coefficients have been used to estimate the confidence limits of changes in *uncorrected* acuity measurements at a specified time i.e. if an observed change is real or within the bounds of chance variation. If it is accepted that a real change in *uncorrected* acuity would have to be two standard deviations outside the average variability, then for Snellen acuity this would constitute a doubling of the minimum visual angle. For example, an *unaided* visual of acuity of 6/6 would have to change to 6/12 before being accepted as a real change. For the Bailey-Lovie chart (or similar charts), a similar acuity of 6/6 would have to change to 6/9 before being considered as a real change.[87]

3.3.2 Visual acuity and cataract surgery

Irrespective of the type of procedure (intracapsular or extracapsular) or type of optical correction (spectacles, contact lenses, or intraocular lens implant), many studies have shown that cataract extraction will improve visual acuity after surgery.[88][89][90][91][92] The length of follow-up for the post-operative assessment varied in these studies as did the type of surgery performed, and all related to practice up to the mid 1980s. All reported that about 80% of patients achieved a best corrected visual acuity of 6/12 or better at the time of the post-operative assessment. If eyes with no other ocular comorbidity are considered, 90% of patients achieved such an outcome.[89][90][91][93]

3.3.2 Complications associated with cataract surgery

The types of complications that occur as a result of surgery depend partly upon the type of procedure and type of intraocular lens implant used.[94][95] These are usually specific to cataract extraction and represent the risks associated with this intervention. Complications are clinically defined and classified in terms of severity according to the resultant effect on vision e.g. whether they are sight threatening or not, whether they are transient or not, or whether they have long term sequelae impairing visual acuity. The complications are usually clinically diagnosed and may or may not require specific diagnostic tests to confirm them. Those most commonly associated with cataract extraction are summarised in Table 1.1. Most of these complications are amenable to treatment. Sight threatening complications, such as endophalmitis and retinal detachment, are infrequent events.

Table 1.1 Types of complications associated with cataract surgery.[95]

Complication	Type of Cataract Extraction
Capsule rupture	Both
Vitreous loss	Both
Expulsive haemorrhage	Both
Hyphaema	Both
Wound leak	Both
Raised intraocular pressure	Both
Corneal oedema	Both
Uveitis	Both
Endophthalmitis	Both
Pupillary block	ICCE > ECCE
Vitreous touch	ICCE > ECCE
Vitreous wick syndrome	ICCE > ECCE
Cystoid macular oedema	ICCE > ECCE
Retinal Detachment	ICCE > ECCE
Residual lens matter	ECCE
Posterior capsule thickening	ECCE

ICCE : intracapsular cataract extraction
ECCE : extracapsular cataract extraction

Improvements and developments in intraocular lens quality and design progressing from anterior chamber lenses and some form of iris fixated lenses to posterior chamber lenses, have reduced the occurrence of complications.[96] Compared to other types of intraocular lenses, posterior chamber lenses are associated with a lower occurrence of complications as seen in Table 1.2.[97]

Table 1.2. Complications associated with intraocular lens implants.[97]

Complication	Type of Intraocular Lens Implant			
	AC %	IF %	IC %	PC %
Cumulative (0 to 12 months):				
Number of eyes	3587	538	1213	2703
macular oedema	8	6.3	2.8	3.5
secondary glaucoma	5.5	4.3	0.7	1.6
hyphaema	4.9	3.2	2.6	1
lens dislocation	0.2	5.6	1.1	0.4
pupillary block	0.8	0.6	0.2	0.3
retinal detachment	0.9	0.4	0.2	0.5
endophthalmitis	0.1	0.2	0	0
Persistent at one year :				
Number of eyes	4132	538	1213	2465
macular oedema	2.2	2.4	0.3	0.8
secondary glaucoma	1.2	0.9	0.1	0.5
hyphaema	0.1	9	0.1	0.3
iritis	1.2	9.9	0.4	1
corneal oedema	1.2	1.5	0.6	0.6
capsule thickening	0.1	0.2	0	0

AC : anterior chamber lens implant
IF : iris fixation lens implant
IC : irido-capsular lens implant
PC : posterior chamber lens implant

3.4 Patient Perceived Measures of Cataract Surgery

3.4.1 Functional Status

Ophthalmologists and other health care workers involved with patients with visual problems have always, albeit implicitly, considered functional status and quality of life (impact on social interactions), together with impairment (visual acuity), when assessing patients and their needs for eye health care. This is usually done in the context of a clinical assessment and may not be necessarily recorded in any formal or standardised manner as other clinical information might be. This emphasis on the assessment of function (however implicit or brief it may be) is demonstrated in the various definitions of blindness.[98] In the UK this definition includes the term "to be unable to perform any work for which eyesight is essential".[99][100] This is the definition used when patients are placed on the blind register in this country. The purpose of the register is primarily for social purposes to meet the needs of blind or partially sighted persons, rather than for their medical needs.

Whilst symptoms and global questions on vision are usually asked in the context of the clinical assessment of the patient, they are not usually recorded in any systematic or standardised fashion. Improvements in symptoms[92][88] and global measures of vision have been reported, [92[88][101][102] but again these were related to practice up to the mid 1980's.

Consequently the measures of functional status that have been developed for use in ophthalmology have been based on clinical experience of the problems patients have reported as being due to their vision. The measures that have been developed relate predominantly to cataract and have been measures of visual function in varying forms of complexity.[101][102][103][104]105][106] The term visual function is used in this thesis to refer to functioning or performance in everyday activities that are dependent on vision.

Only a few studies have explicitly considered the concept of assessing functioning in activities dependent on vision and other aspects of the patient's daily life after cataract

surgery. These studies were conducted on patients having surgery before the mid 1980s, during periods where intracapsular extraction was the usual practice with glasses or contact lenses for aphakic correction,[88][92][107][108] or during periods of transition to extracapsular extraction and the introduction of intraocular lenses.[109[110][111][112] The findings reported were not necessarily related to the surgical practice i.e. type of procedure or optical correction used.

Where intracapsular surgery had been performed and aphakic correction provided predominantly by high powered spectacles, a discrepancy between visual acuity and functional status post-operatively was observed. Whilst the majority of patients were able to demonstrate good visual acuity with their correction, about 39% were not able to utilise this acuity for reading or for performing other routine vision-dependent tasks.[107] Up to 26% reported no change or dissatisfaction with their ability to perform routine tasks after surgery and two thirds of patients had problems in performing routine tasks with their aphakic correction.[88] This discrepancy between visual acuity achieved and ability to utilise it in routine activities was particularly evident in monophakic patients and those who had been moderately disabled pre-operatively.[108] These problems would not have been identified by conventional assessment of outcome by visual acuity alone. A subsequent study using similar methods for assessing post-operative function, demonstrated that the majority of patients having an iris-fixated intraocular lens were able to achieve a maximum functional status score post-operatively.[113] The discrepancy observed between post-operative visual acuity and post-operative visual functioning was attributed to the optical aberrations associated with aphakic correction, the patients' ability to adjust to them and possibly increasing age.[88][108] Optically, intraocular lenses were able to provide a better quality of post-operative visual acuity and were thus associated with better post-operative functioning.[113]

Improvement in mental health status and physical function (e.g. timed manual performance tests) maintained up to a year after surgery, have also been demonstrated following cataract extraction.[110] Pre-operative visual acuity and baseline functional status, including mental health state, are important factors determining long term functional benefit.[111]

3.4.2 Health-Related Quality of Life

There has been no assessment of the impact of cataract surgery on health related quality of life.

4. SUMMARY

Cataract is a common condition causing visual impairment and blindness. In the UK it particularly affects the elderly population.

There have been significant developments in the surgical technique for cataract extraction and in the technology for optical correction of aphakia, in the last 25 years. It is possible that these may have influenced the outcomes of cataract surgery. The current literature refers predominantly to surgical practices and clinical outcomes that are either outdated (intracapsular surgery) or were performed during periods of changing surgical techniques from intracapsular extraction to extracapsular extraction with varying types and design of intraocular lens. Whilst it was likely that surgical practice had stabilised by the time this thesis had started, there was no evidence to support this assumption. Surgical practice for cataract extraction and its variations in this country were not known accurately at that time.

Cataract extraction is a high volume surgical procedure within the National Health Service (NHS) which is associated with a significant improvement in post-operative visual acuity. Changes in surgical practice and optical correction have reduced the serious sight threatening complications of surgery and improved the optical quality of post-operative visual acuity. This may have reduced the thresholds at which surgery may be considered to be worthwhile and is indirectly observed by the falling levels of visual acuity on admission from blindness to 6/60 between 1970 to the mid 1980s. In addition, technical advances have made surgery possible for patients who would previously not have been suitable, particularly those with ocular comorbidity. This, combined with changes in the age structure of the population, has probably contributed to the greater demand for surgery.

Although this is a trend which is likely to continue, the situation regarding current surgical practice and its outcomes in the United Kingdom remains unknown.

The benefit of cataract surgery has so far, usually been measured exclusively by a single clinical indicator, improvement in visual acuity and, to a lesser extent surgical complications. Whilst surgical practice has developed to improve the quality of the vision restored after surgery, little is known about its impact on patients' functioning in routine activities and on their quality of life, particularly in the context of the process of care provided in established surgical practice for extracapsular cataract extraction and intraocular lens implantation. The influence of ocular and other comorbidity on the outcome of current surgical practice has not been established. This is probably because the methods required for such assessments have not been widely available nor applied to vision-related problems.

5. AIMS AND OBJECTIVES

The aim of this thesis was to compare methods for the assessment and measurement of clinical impairment (visual acuity), and patient perceived measures of disability (functional status) and handicap (quality of life) that may be used to evaluate the impact of cataract surgery.

The aims of this thesis was to be achieved through the following objectives :

1. To describe current surgical practice for age-related cataract in the UK

2. To describe the clinical outcomes of cataract surgery

3. To identify risk factors for a poor clinical outcome

4. To describe the impact of cataract on visual acuity (impairment), visual function (disability), and health related quality of life (handicap) and determine their inter-relationships.

5. To describe the short term (at three months), and medium term (at twelve months) outcomes of cataract surgery in terms of visual acuity, visual function and their inter-relationships.

To achieve these objectives, two major studies were undertaken. First, a national prospective cohort study was conducted to consider surgical practice and clinical outcomes. This is presented in chapters 2 and 3. Second, a smaller, but more detailed prospective cohort study was undertaken in three hospitals to consider both clinical (visual acuity), and patient perceived measures of outcome (visual function and quality of life). This is presented in chapters 4 to 8. The findings relating to each of the objectives of

this thesis will be discussed in the relevant chapters. In chapter 9 the use of the methods for measuring and assessing impairment, disability and handicap in practice (patient-based) and for epidemiological health services research (population-based) and their specific contribution to the evaluation of the impact of cataract surgery are discussed.

At the time this work was started, this area of research was just beginning to receive some interest and there was an opportunity to collaborate with colleagues on the Cataract Patient Outcomes Research Team (PORT), based at Johns Hopkins University, Baltimore, USA. To achieve this, standardised measures of functional status and health related quality of life were used. In doing so, this collaboration provided the opportunity to assemble comparable data for different populations in different health care settings.

Chapter 2.

THE NATIONAL CATARACT SURGERY STUDY : METHODS

1. INTRODUCTION

This and the following chapter will be concerned with the clinical outcomes of cataract surgery. Since accurate and complete information on current surgical practice and its outcomes was not available either from routine sources or the literature, a national study was conducted - the National Cataract Surgery Study. It's objectives were :

a. to describe the current surgical management of cataract in the NHS

b. to describe the short term clinical outcomes of cataract surgery

c. to identify risk factors for poor clinical outcome

2. STUDY DESIGN

A prospective cohort design was chosen to describe current surgical practice and clinical outcomes within the NHS. When related to population denominators, this design would provide information on the frequency of the intervention (cataract surgery). In addition, information on the characteristics of current surgical practice could be obtained, and an opportunity to identify risk factors for poor clinical outcome was available.

In order to ascertain the short term outcome, patients were followed up for three months after surgery. This period of follow-up was chosen as a clinical consensus suggested that by this time optical rehabilitation following surgery should have been established, and patients would have been discharged, or be ready for discharge, from care.

A national approach was adopted with all ophthalmic departments in the United Kingdom invited to participate, so that an assessment of overall practice in the NHS could be made. Whilst this involved data collection on a wide scale, raising concerns regarding administration, monitoring, and follow-up, it allowed a large sample to be obtained rapidly. The survey period was one week : 26 to 30 November 1990. The study centre was the Royal College of Ophthalmologists, London.

3. SAMPLE SELECTION

The aim was to obtain a representative sample of patients undergoing cataract surgery within the NHS. It was assumed that, beyond administrative and managerial constraints, consultant ophthalmologists were responsible for the clinical management of patients. In order to describe clinical practice it was essential to obtain data on the actual management of patients and not the consultant's opinion of how his/her patients were managed.

The sampling frame consisted of *all* consultants who regularly performed surgery for age-related cataract. Consultants holding NHS appointments were identified from the Royal College of Ophthalmologists' database and were asked to confirm that they had patients under their care for cataract surgery, and that they performed at least one operating list per week for these patients. Only consultants fulfilling both criteria were regarded as eligible. Consultants were ineligible if they only performed specialist ophthalmic surgery (e.g. paediatric, vitreo-retinal), or if they were medical or academic ophthalmologists.

All eligible consultants were invited to participate by providing *clinical* data on all patients (fulfilling the inclusion criteria), admitted under their care for cataract surgery during the study week. All patients of 50 years of age and over, admitted for surgery for age-related cataract during the study week, were eligible for inclusion. Those patients undergoing combined procedures or surgery for other types of cataract (e.g. traumatic, congenital, iatrogenic), were excluded.

4. SAMPLE SIZE

It was estimated that there were about 500 consultants providing a cataract surgical service (as defined above), and that they each had about 5 admissions per week that could be eligible for inclusion in the study. Thus it was expected that about 2,500 patients would be admitted for surgery. It was anticipated that 60% to 80% of consultants would participate, providing a cohort of between 1500 and 2000 patients.

About 20% of patients have been reported to have a poor visual outcome following cataract surgery. Assuming that all estimates would be based on 95% confidence limits, a sample of 693 patients would give a precision of +/- 2.5% or better (e.g. 95% confidence limits of 17.5% to 22.5%) for a finding of 20% poor visual acuity outcome. [114] Similarly for cystoid macula oedema and sight threatening complications of surgery such as retinal detachment which are infrequent events that may occur in

about 1% of patients, it was estimated that a sample of 885 patients would give a precision of +/- 0.55% or better (e.g. 95% confidence limits 0.45% to 1.55%) to detect this level of complication occurring. [114]

5. CONDUCT OF THE STUDY

All eligible, consultant ophthalmologists were informed of the purpose and objectives of the study. They were told that their participation would require them to provide clinical data on patients admitted under their care for cataract surgery, and assurances were given regarding the maintenance of confidentiality of the data collected. They were also asked to indicate if they did not wish to participate, giving their reason(s) if possible.

A prospective design was preferred to allow for collection of specific data for the study. In order that this design would not influence practice (a Hawthorne effect), or influence the selection of patients for inclusion in the study, each consultant was only informed of the study period on the last working day before or on the morning of the first day of the study week. Sufficient survey forms (Appendix A1) for data collection were supplied to each consultant at this time together with specimen forms and instructions for completion. Additional forms had to be obtained from the study centre.

Consultants were reminded of the three month post-operative assessment shortly before it was due to take place. A general reminder in "College News", the Royal College of Ophthalmologists' quarterly newsletter, followed by an individual reminder were circulated after the three month follow-up period, to encourage return of any outstanding data that had not already been returned to the study centre.

All data were entered on a customised computer database using Paradox 3.0 software, at the Royal College of Ophthalmologists, and held in accordance with the Data Protection Act 1984.

Ethical permission for the study was not sought as only data that would be collected in routine clinical practice was required for the Study, and no additional examinations or procedures were being performed on patients.

6. DATA COLLECTION ON PATIENTS

Individual patients were identified by a code ascribed by the study centre, to ensure confidentiality. Data collection on such a wide scale concentrated on those items that would reasonably be expected to be : part of the routine assessment for cataract patients at the pre-operative assessment; recorded in the operation notes; and recorded at follow-up in the out-patient clinic after surgery. Only *clinically evident* comorbid ophthalmic conditions and *clinically evident* complications related to the surgical procedure were sought. It is unlikely that this would have excluded more than just a few, subtle, minor conditions or events, that were not directly identifiable from routine clinical examination without further diagnostic investigations

Before surgery, the following data obtained from the clinical history and ophthalmic examination, were collected on each patient : best corrected visual acuity in each eye at the time of listing for surgery and on admission; and *clinically* evident ocular comorbidity.

Data on the surgical procedure included : the length of hospital stay (in-patient or day case); the type of anaesthesia used (general or local); the type of procedure performed; the grade of surgeon performing the procedure; and the occurrence of intra-operative complications.

Three months after surgery information was obtained on whether the patient had been discharged from follow-up or not and whether visual rehabilitation by this time had been achieved (i.e. had a final refraction been performed and glasses dispensed). The clinical outcomes of interest included the traditional indicators of change in best corrected Snellen visual acuity at three months post-operatively in the eye that had been operated on, and the occurrence of complications.

Visual acuity is presented as best corrected Snellen acuity. A poor visual outcome was defined as visual acuity at three months after surgery of less than 6/12 (that is 6/18 to blind). Acuity of 6/12 is the minimum legal requirement for a driving licence in the UK[115] and was taken as an acceptable level of visual acuity.

A complication was defined as an event that was a consequence of the surgical procedure, that would not have otherwise occurred. The occurrence of *clinically* evident complications during the surgical procedure, in the immediate post-operative period (within 24 hours of surgery), by the first post-operative out-patient assessment (within one month of surgery), and at three months after surgery, were recorded.

(The data collection forms are provided in Appendix A1).

7. DATA COLLECTION ON CONSULTANTS

Information on consultants' clinical activity was also collected. This included the number of operating and out-patient sessions available per week for each consultant. These were examined for the study week, the weekly average for the period immediately prior to the study (January to September 1990), and the weekly average for the preceding year 1989. This was ascertained by the consultants and their clerical staff from theatre diaries and out-patient clinic bookings for those periods.

(The data collection forms are provided in Appendix A1).

8. STATISTICAL METHODS

Snellen visual acuity, unless otherwise indicated, was treated as a categorical variable and grouped as follows [87] :

good visual acuity	-	6/6 to 6/12
moderate impairment	-	6/18 to 6/24
severe impairment	-	6/36 to 6/60
blind	-	less than 6/60

Age was considered as both a continuous variable and a categorical variable. In the latter case, age was grouped as follows :

3 groups -

- 50 to 64 years
- 65 to 74 years
- 75 years and over

2 groups -

- less than 75 years
- 75 years and over

If more than one comorbid ocular condition was recorded, that which was considered to be the most severe by the attending ophthalmologist was taken for analysis. Similarly, if more than one type of complication occurred, that which was considered to be the most severe by the attending ophthalmologist was taken.

The data were predominantly descriptive. Where appropriate, 95% confidence levels are provided for the estimates obtained. The 95% confidence intervals around proportions were calculated by the normal approximation to the binomial distribution for large proportions and by the exact method for smaller ones [116]. For continuous data (e.g. age), the unpaired t-test was used to test the significance of an observed difference between the mean values of sub-groups. The Chi-square test was used to determine

whether the observed differences in proportions between sub-groups (e.g. by age and sex) were statistically significant.

Cumulative incidence is used as a measure of frequency for complications occurring at the specified post-operative periods. It is given by the ratio of the number of patients who developed complications during a given period to the number of patients at the beginning of that period. It indicates the average risk a patient has of developing a complication in the specified period of time.

Multivariate regression analysis methods were used to determine prognostic factors for poor clinical outcome using the EGRET (Epidemiological Graphics, Estimation and Tabulation) statistical programme [117]. The variables for poor clinical outcomes included:

- poor visual acuity at 3 months after surgery
  (defined as best corrected Snellen acuity in the surgery eye of less than 6/12)

- the existence of any complications at 3 months after surgery.

These clinical outcomes were dichotomous variables i.e. poor clinical outcome did or did not occur. Risk factors for poor visual outcome and risk factors for complications were considered separately.

Prior to multivariate regression modelling, bivariate cross-tabulations between the dependent (outcome) variables and the other independent variables of interest, were scrutinised to identify extreme correlations that might produce troublesome collinearities in the modelling. Also the associations between each independent variable and the dependent (outcome) variable were looked at when stratified by all the remaining variables, one at a time, in order to identify any obvious effect modification (interactions).

A Poisson logistic regression model was fitted, first, with only the main variables of interest. This was then followed by fitting all the other variables of interest (including those

considered to be confounders) in a stepwise Poisson logistic regression model. The variables that demonstrated a significant effect on outcome, having adjusted for all the other variables in the stepwise model, were then fitted in a further regression model together with other possible confounding variables to evaluate their relative risks. (Details of the models used are provided in Appendix A2 and A3).

Poisson regression was used because it provides an estimate of the relative risk for poor clinical outcome in a multivariate framework. The Poisson distribution provides a good approximation to the binomial distribution for rare events. It was assumed that as a patient could only experience a poor clinical outcome once (either visual acuity or a complication), depending on the model, the occurrence of these events could be treated as Poisson events.

The relative risk is a measure of the strength of an association between a factor and the outcome of interest. In this case the relative risk was calculated as the ratio of the cumulative incidence of poor clinical outcome (visual acuity or a complication) among those patients with the variable of interest, such as ocular comorbidity, compared with those patients that do not have ocular comorbidity. It provides an estimate of the risk or probability of a poor clinical outcome associated with that factor.

9. SUMMARY OF METHODS

The methods used to achieve the objectives of this study may be summarised as follows :

- The study method was that of a prospective cohort design.

- The measures of outcome were clinical. These were visual acuity in the eye that had surgery and complications.

- The main statistical methods provided measures of risk. Cumulative incidence provided and estimate of the average risk of an event of interest occurring. Poisson regression analysis provided estimates of relative risk as measures of effect between cataract extraction and poor clinical outcome.

Chapter 3.

THE NATIONAL CATARACT SURGERY STUDY : RESULTS

1. RESPONSE

At the time of the study, there were 14 NHS regions in England, plus Wales, Northern Ireland, and for the purposes of the study, Scotland was divided into two regions. In addition, one special health authority provided a regular surgical service for age-related cataract. Although this special health authority provided a service predominantly for patients in its neighbourhood, it also treated patients from further afield.[118] For this reason and because of its size (number of consultant staff) it was considered independently of other areas. This made a total of 19 areas.

There were 527 eligible consultant ophthalmologists in the UK who regularly performed surgery for age-related cataract based in 183 ophthalmic departments. 157 (86%) of the departments participated, with every area in the UK represented.

The participation rate of eligible consultants was 66.2% (n= 349). 1498 patients were admitted for surgery, representing an estimated 86% of all possible admissions. (Figure 3.1)

Figure 3.1
Estimates of completion of reporting of all possible eligible cases for inclusion in the study

527 eligible consultants likely to contribute about 5 operations each per week

↓

Estimated number of admissions during study week in whole of the UK
n = 2635

↓

Participating consultants
n = 349

↓

Estimated number of admissions by participating consultants during study week
n = 1740

↓

Reported number of admissions during study week
n = 1498

↓

Reported number of operations performed during study week
n = 1445

↓

Follow-up data at 3 months
n = 1153

↓

complete data for visual acuity n = 959

complete data for complications n = 998

As shown in Table 3.1, responders and non-responders were similar in respect of the 3 main characteristics, and no significant differences were demonstrated.

Table 3.1 Comparison of participating and non-participating consultants.

	Participants		Non-Participants	
Characteristic	**N**	**(%)**	**N**	**(%)**
Type of Hospital :				
Teaching	83	(23.8)	36	(20.2)
District	212	(60.7)	112	(62.9)
Eye	54	(15.5)	30	(16.9)
Total:	349	(100)	178	(100)
	Chi square=0.89, df=2, p=0.64			
Size of Unit- Number of Consultants :				
<=2 Consultants	87	(24.9)	47	(26.4)
3 Consultants	99	(28.4)	40	(22.5)
4 Consultants	57	(16.3)	28	(15.7)
>4 Consultants	106	(30.4)	63	(35.4)
Total:	349	(100)	178	(100)
	Chi square=2.61, df=3, p=0.46			
Years since Appointment as Consultant :				
5	93	(23.3)	41	(26.3)
10	73	(22.1)	36	(23.1)
15	59	(17.8)	32	(20.5)
20	56	(16.9)	28	(17.9)
25	42	(12.7)	14	(8.97)
30	8	(2.42)	5	(3.21)
Total:	331	(100)	156	(100)
	Chi square=2.17, df=5, p=0.82			

2. SURVEY PERIOD

Figures 3.2 and 3.3 present the distributions of the number of out-patient sessions and theatre sessions that were available for each consultant during the survey week, the period preceding it (January-September 1990), and the average number of these sessions available in the preceding year. When considered in these terms, the survey week was typical and did not exhibit any statistically significant differences with respect to activity in recent times: out-patient sessions Chi-square=5.35, df=14, p-value=0.98; theatre sessions Chi-square=9.35, df=10, p-value =0.49.

Figure 3.2 Activity : Out-Patient Sessions

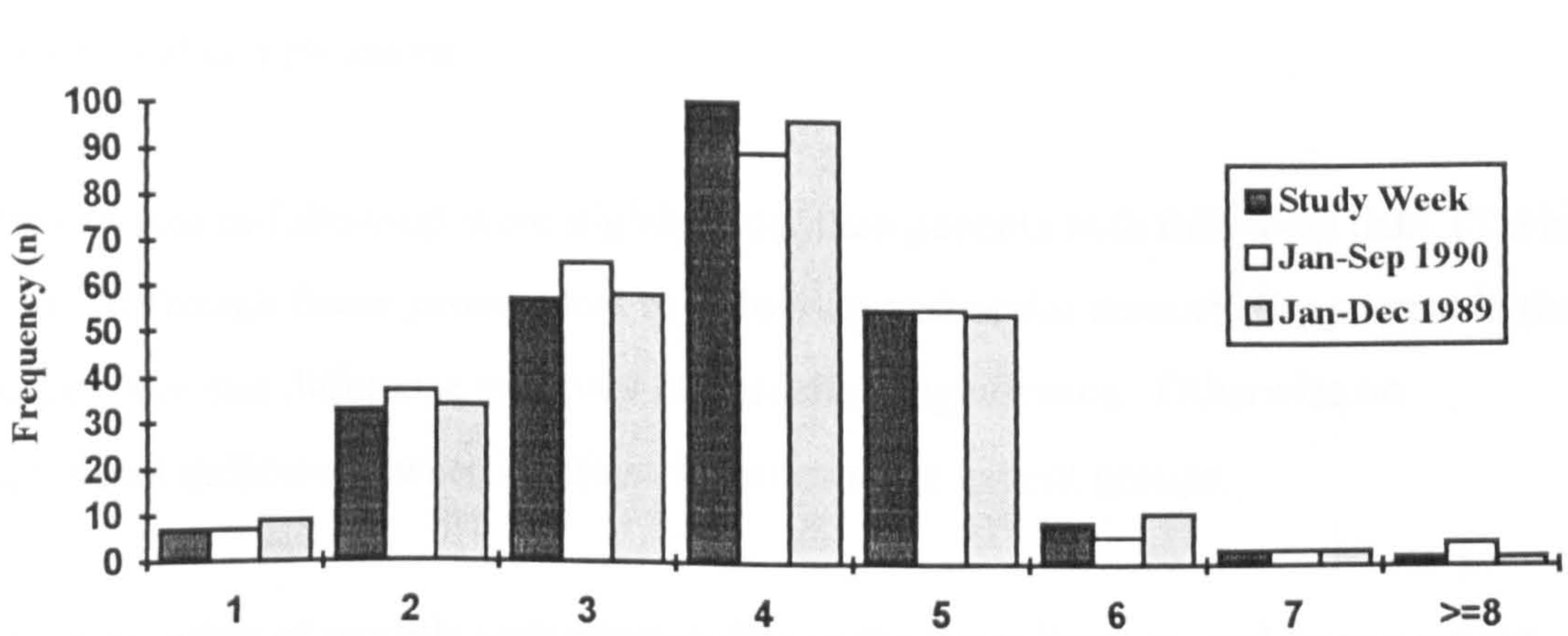
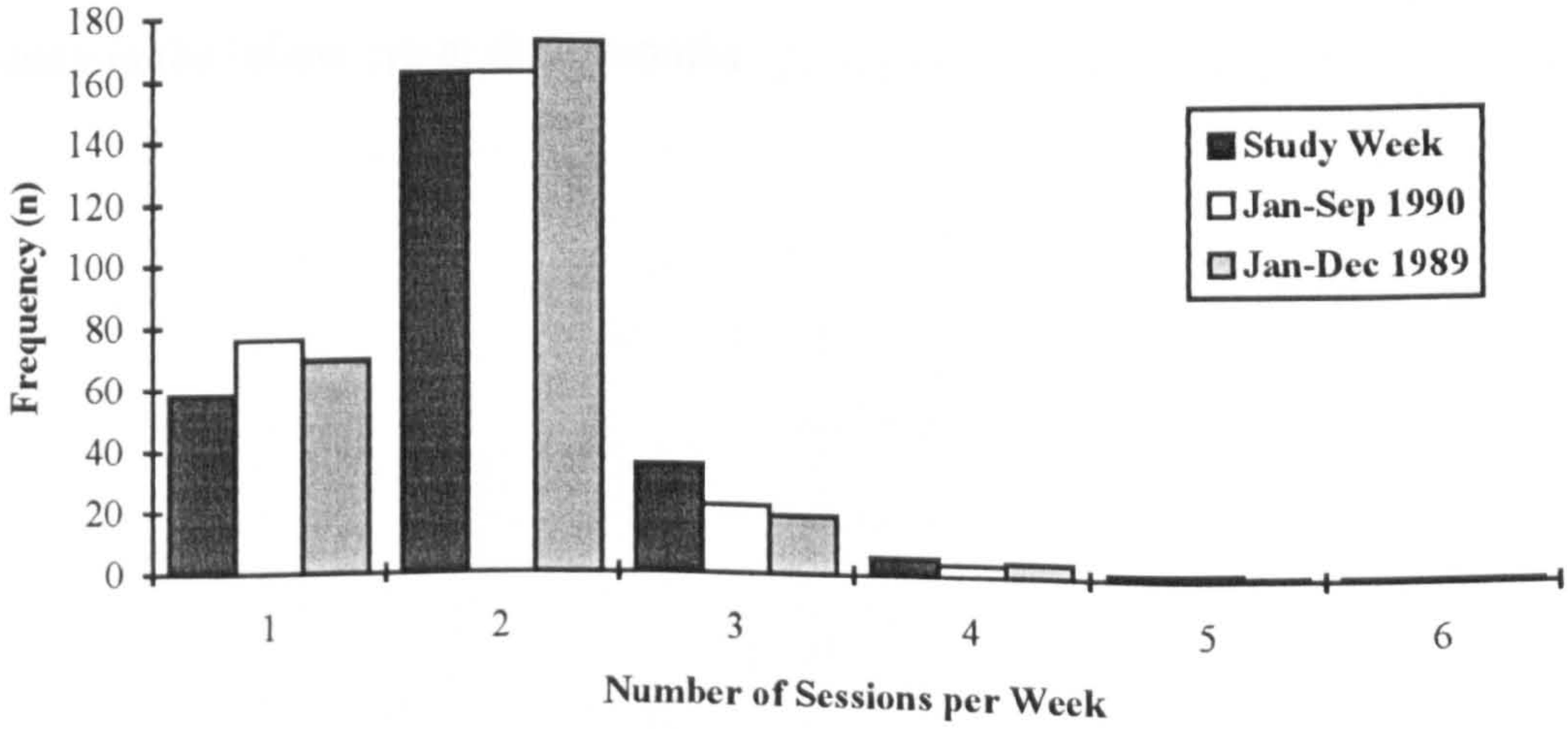


Figure 3.3 Activity : Theatre Sessions



3. LOSSES TO FOLLOW-UP AND D ATA COMPLETENESS

1498 patients aged 50 years or more were reported by the participating consultants as having been admitted for cataract surgery during the study week. Of these, 1445 patients had surgery performed during the study week. Of the 53 patients that did not have surgery, 20 patients had surgery cancelled for medical reasons, with no reason specified for the remaining 33 patients.

Data on 1153 (80%) patients were available for post-operative follow-up at three months. No reason was ascertained for losses to follow-up despite reminders and requests. Of these 1153 patients, 959 had complete records for visual acuity (pre-operatively and at three months after surgery), and 998 patients had complete records for surgical complications.

Patients lost to follow-up were slightly older than patients with follow-up data (Table 3.2). Although fewer patients lost to follow-up had ocular comorbidity present in the surgery eye this difference was only of borderline significance. Otherwise no significant differences were identified between these patient groups.

The proportion of records with missing data in the items listed ranged from zero for age to 17% for the visual acuity in the fellow eye at three months (Table 3.3). Most items had complete data for at least 90% of patients with the exception of : eye order (right or left eye); whether glasses had been dispensed by three months; and visual acuity in the fellow eye at three months.

Table 3.2 Characteristics of patients followed up after surgery and those lost to follow-up.

	Patients Followed Up n=1153 n (%)	Patients lost to Follow-Up n=345 n (%)
Age on admission (yrs)		
50-64	157 (13.6)	36 (10)
65-74	356 (31)	93 (27)
>=75	640 (55.5)	217 (63)
	Chi-square=5.97, df=2, p=0.05	
Sex		
males	446 (38.7)	130 (38)
females	706 (61.3)	214 (62)
	Chi-square=0.09, df=1, p=0.76	
Visual Acuity on admission in Surgery Eye		
6/6 to 6/12	80 (7)	22 (7)
6/18 to /624	265 (24)	70 (21)
6/36 to 6/60	246 (22)	86 (26)
less than 6/60	528 (47)	154 (46)
	Chi-square=2.60, df=3, p=0.46	
Ocular Comorbidity on Admission in Surgery Eye		
present	460 (41)	116 (35)
absent	656 (59)	213 (65)
	Chi-square=3.76, df=1, p=0.052	
Type of Admission		
In-patient	77 (7)	34 (10)
Day-case	1010 (93)	300 (90)
	Chi-square=3.4, df=1, p=0.065	

Table 3.3 Data Quality - Completeness of Recording

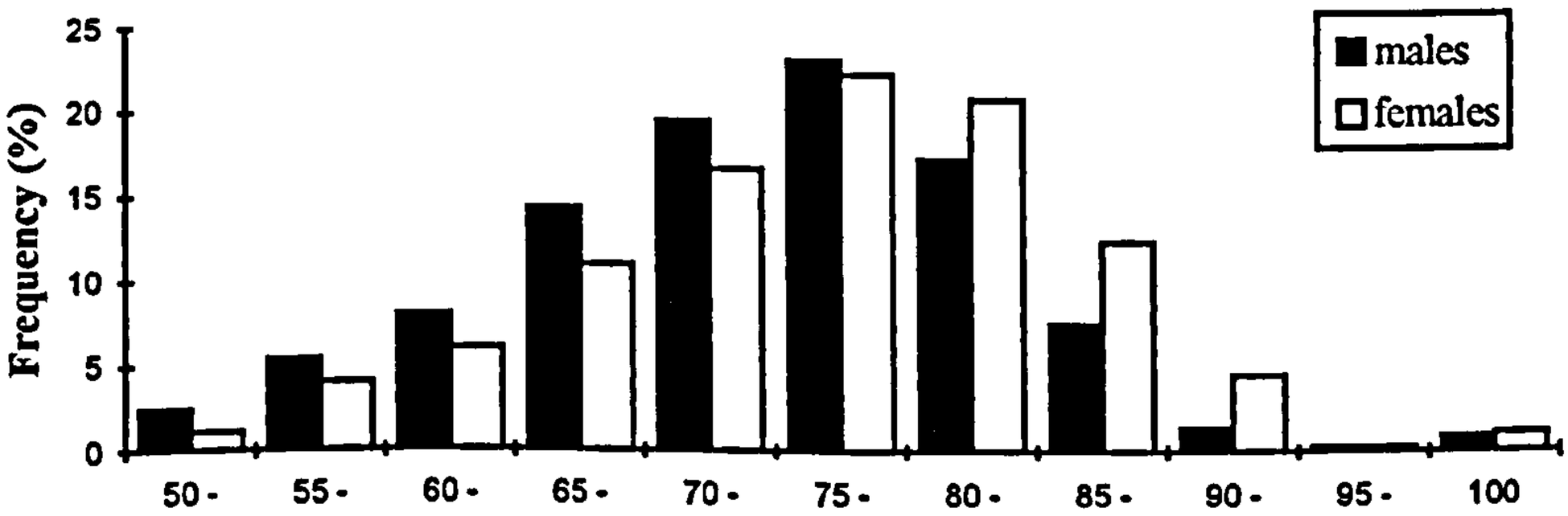
Field	Total Number Records	Number of Records with Missing Data	% Records Missing Data
On Admission (n=1498 patients admitted in survey period) :			
Age	1498	0	0.0
Sex	1498	4	0.3
Ethnic group	1498	51	3.4
Eye order - first or second eye	1498	214	14.3
Visual Acuity - surgery eye	1498	31	2.1
Visual Acuity - fellow eye	1498	60	4.0
Ocular Comorbidity (any eye)	1498	91	6.1
Patients that had surgery performed (n=1445) :			
Admission type - in-patient or day case	1445	75	5.2
Anaesthetic used - local or general	1445	18	1.2
Grade of surgeon	1445	11	0.8
Intra-operative complication	1445	21	1.5
Immediate complication	1445	25	1.7
Post-operative Follow-Up (n=1153 paired records):			
1 month complication	1153	44	3.8
Status at 3 months - discharge	1153	78	6.8
Glasses dispensed by 3 months	1153	183	15.9
3 month complication	1153	103	8.9
Capsulotomy indicated at 3 months	1153	100	8.7
Visual Acuity - surgery eye at 3 months	1153	61	5.3
Visual Acuity - fellow eye at 3 months	1153	197	17.1

4. PATIENT CHARACTERISTICS

4.1 Age and Sex

There were 575 males and 919 females, a male : female ratio of 1 : 1.6. The age and sex distribution is presented in Figure 3.4. The mean age of patients on admission for cataract surgery was 75.9 years (95% C.I. 75.4 to 76.4). Females were slightly older than males, having a mean age of 76.8 years compared to a mean age of 74.4 years for males. The difference in mean age of 2.4 years between males and females was statistically significant (p-value <0.001, unpaired t-test). Overall 61% (n=853) of patients were 75 years of age and over. 563 (61%) of females were 75 years or over, compared with 290 (50%) of males.

Figure 3.4. Age Distribution on Admission for Cataract Surgery



4.2 Ethnicity

96% (n=1387) of patients were Caucasian, 2.8% (n=40) were Asian and 1.1% (n=16) were African-Caribbean.

4.3 Ocular Comorbidity

As seen in Table 3.4, over half of the patients had no other clinically evident ocular morbidity present (n=799) in either eye. Age related maculopathy was the commonest

comorbid condition identified. Most of these patients had moderate macular changes, with a few having severe changes. Only 4% (n=56) of patients had some form of diabetic eye disease. This was predominantly background retinopathy (n=30). Other less common conditions included corneal pathology (scarring secondary to infection/inflammation, and corneal dystrophies), retinal degenerations, vasculopathies and old retinal detachment and common lid disorders.

Table 3.4 Comorbid Ocular Conditions Present on Admission for Surgery.

	EITHER EYE			SURGERY EYE		
Type of Comorbidity	**N**	**%**	**95% C.I.**	**N**	**%**	**95% C.I.**
None Present :	799	56.8	54.2 to 59.4	887	65.5	62.9 to 68.0
Age Related Maculopathy :	173	12.3	10.6 to 14.0	127	9.4	7.9 to 11.1
Drusen / RPE changes	(153)	(10.9)		(121)	(8.9)	
Disciform	(20)	(1.4)		(6)	(0.5)	
Diabetic Retinopathy :	56	4	3.0 to 5.1	48	3.5	2.6 to 4.7
Background	(30)	(2.1)		(26)	(1.9)	
Proliferative	(8)	(0.6)		(7)	(0.5)	
Maculopathy	(18)	(1.3)		(15)	(1.1)	
Glaucoma :	148	10.6	8.9 to 12.1	137	10.1	8.5to 11.7
Amblyopia :	34	2.4	1.7 to 3.4	14	1.0	0.6 to 1.7
Other * :	197	14.1		142	10.5	
TOTAL :	1407 #	100		1355 ##	100	

* "Other" includes conditions such as common lid disorders, retinal degenerations, vasculopathies, corneal scarring/dystrophy, previous retinal detachment

\# presence of ocular comorbidity was not known for 91 patients

\## presence of ocular comorbidity and which was the surgery eye (right or left) was not known for 143 patients

468 patients (34.5%), had some clinically evident comorbid ocular conditions in the surgery eye on admission. As seen in Table 3.5, the proportion of patients with ocular comorbidity in the surgery eye rose with age. The differences observed between the sub-groups by age were significant (chi-square=5.1, df=2, p-value=0.0005). No gender differences were observed for the presence or absence of ocular comorbidity.

Table 3.5 Ocular Comorbidity on Admission in Surgery Eye by Age and Sex

	Ocular Comorbidity in Surgery Eye	
	Absent n (row%)	**Present** n (row%)
Age Group (years) :		
50 to 64	134 (74.4)	46 (25.6)
65 to 74	283 (69.4)	125 (30.6)
>=75	470 (61.3)	297 (38.7)
All	887 (65.5)	468 (34.5)
	Chi-square=15.1; df=2; p-value=0.0005	
Sex :		
males	356 (68.2)	166 (31.8)
females	527 (63.6)	302 (34.6)
All	883 (65.4)	468 (34.6)
	Chi-square=3.0; df=1; p-value=0.08	

4.4 Visual Acuity on Admission

Table 3.6 presents the visual acuity in the surgery eye and in the better eye on admission. 47% (n=677) of patients were blind in the surgery eye on admission. About half of these patients (n=320) had no other ocular morbidity identified, and were admitted for surgery to an eye blinded by cataract. The median acuity on admission for the surgery eye was 6/60.

The median acuity on admission in the better eye was 6/18. Less than half (45%, n=647) of the patients had good visual acuity in the better eye.

Table 3.6 Visual Acuity on Admission.

Visual Acuity Group	Surgery Eye n	%	Better Eye n	%
6/6 to 6/12	101	7.0	647	45.0
6/18 to 6/24	333	23.1	373	25.9
6/36 to 6/60	333	23.1	175	12.2
less than 6/60	677	46.9	243	16.9
All	1444*	100.0	1438#	100.0

* complete records for visual acuity in surgery eye
\# complete records for visual acuity in better eye

No significant age or gender differences were observed for visual acuity on admission in the surgery eye as seen below in Table 3.7.

Table 3.7 Visual Acuity on Admission in Surgery Eye by Age and Sex

	Visual Acuity in Surgery Eye							
	6/6 to 6/12		6/18 to 6/24		6/36 to 6/60		less than 6/60	
	n	(row%)	n	(row%)	n	(row%)	n	(row%)
Age Group (years) :								
50 to 64	17	(9.4)	44	(23.4)	37	(19.7)	90	(47.9)
65 to 74	33	(7.7)	86	(20.0)	93	(21.6)	219	(50.8)
>=75	51	(6.2)	203	(24.6)	203	(24.6)	368	(44.6)
All	101	(7.0)	333	(23.1)	333	(23.1)	677	(46.9)
	Chi-square=9.4; df=6; p-value=0.15							
Sex :								
males	41	(7.4)	124	(22.5)	120	(21.7)	267	(48.4)
females	60	(6.8)	207	(23.3)	212	(23.9)	409	(46.1)
All	101	(7.0)	331	(23.1)	332	(23.1)	676	(46.9)
	Chi-square=1.4; df=3; p-value=0.7							

5. SURGICAL PRACTICE

5.1 First or second eye

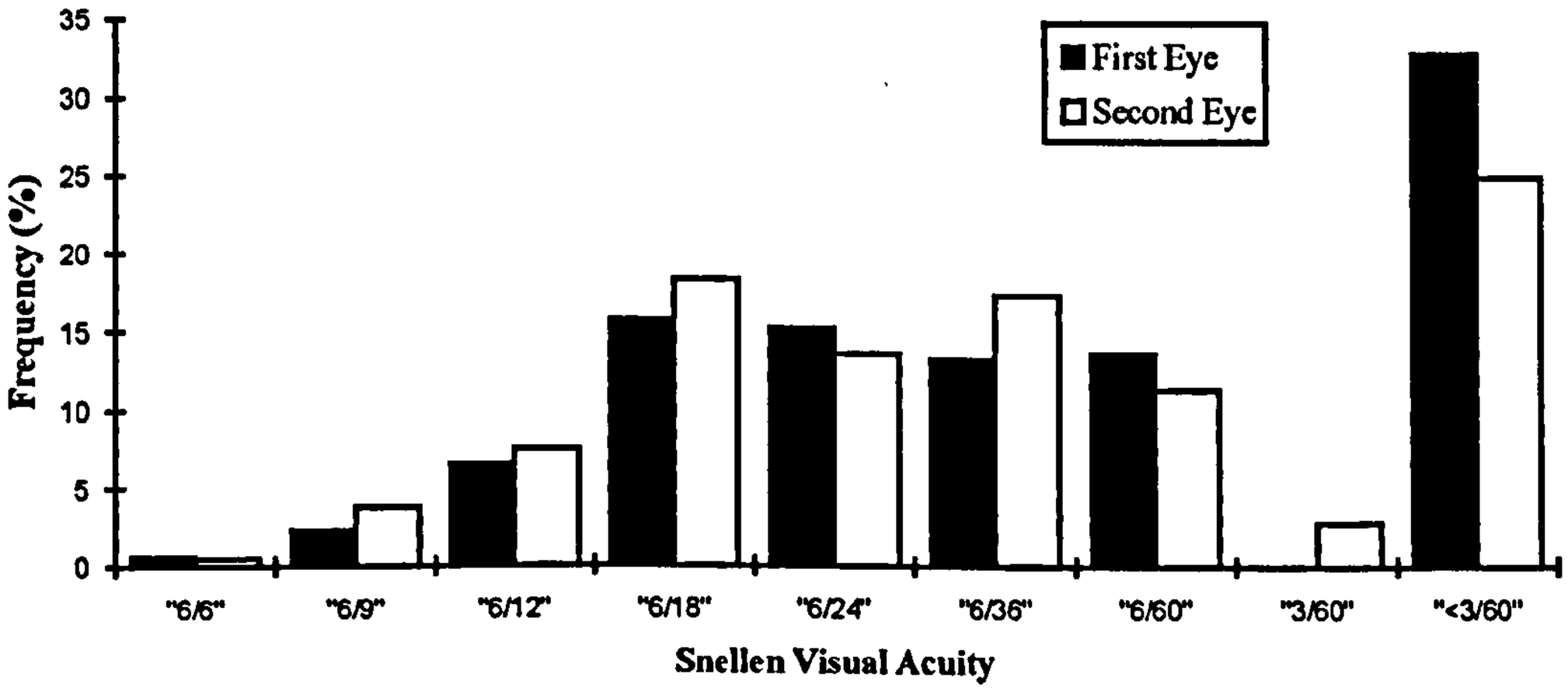
66% of admissions (n=871) were for surgery to the first eye and 34% (n=449) for surgery to the second eye

5.2 Surgical threshold

The distribution of visual acuity in the surgery eye at the time of listing for surgery is presented in Figure 3.5. It was not influenced by being a first or a second eye, with the median acuity being 6/36 in both groups. Although a small proportion of patients had good visual acuity (9.3%, n=81/868 first eyes; 11.3%, n=48/410 second eyes), the

threshold at which most patients were listed for surgery was at 6/18 in both groups. The second peak seen at visual acuity less than 3/60 is the result of combining acuities not related to viewing objects of a specified size at a specified distance, and range from counting fingers to no perception of light. The proportion of patients that were blind (less than 6/60) on listing was 34% (n=434/1278).

Figure 3.5 Visual Acuity in Surgery Eye : At Listing for First & Second Eye



5.3 Features of Practice

These are summarised in Table 3.8. Most patients had surgery as an in-patient procedure (n= 1265, 92%). Local anaesthesia was used in about half of the patients (n=661, 46%). The majority of patients (95%) having a day case procedure had surgery performed under a local anaesthetic block, whilst only 42% of patients having in-patient surgery had a local anaesthetic.

92% (n=1316) of all procedures were standard extracapsular cataract extractions. A further 4% (n=56) of procedures were performed by phako-emulsification - another type of extracapsular procedure. 91% (n=1305) of all patients had an extracapsular procedure with a posterior chamber lens implant. An intracapsular extraction was performed in 4% (n=56) of patients.

59% (n=847) of procedures were performed by surgeons of consultant grade, 35% (n=502) by resident staff (senior registrars 10%, registrars 16%, senior house officers 9%), and associate specialists, clinical assistants or locum staff collectively performed 6% (n=85) of the procedures.

Three months after surgery only one third of patients (n=357/1075) had been discharged. The remainder (n=718) were still being followed-up in the out-patient clinic. 182 patients had no identifiable reason for continued follow-up as they had no surgically related complication and had achieved a good visual outcome.

Table 3.8 Surgical Practice. n = 1445.

	Number	%
Length of Stay :		
day-case	105	8
in-patient	1265	92
missing	75	
Type of Anaesthetic :		
general anaesthetic	766	54
local anaesthetic	661	46
missing	17	
Grade of Surgeon performing the procedure :		
consultant	847	59
senior registrar	146	10
registrar	26	2
senior house officer	130	9
other	85	6
missing	11	
Type of Procedure :		
extracapsular extraction	1316	92
phako-emulsification	56	4
intracapsular extraction	56	4
missing	17	
Type of Intra-Ocular Lens Implant :		
posterior chamber	1312	92
anterior chamber	80	6
none inserted	36	3
missing	17	
Status at 3 months after surgery :		
discharged from clinic	357	33
follow-up in clinic	718	67
missing		

6. CLINICAL OUTCOMES

6.1 Visual Acuity

There were 959 records with complete data. The distribution of visual acuity in the surgery eye before and after surgery, is shown in Table 3.9. Pre-operatively, a small proportion of patients (8%, n=80), had good visual acuity (6/6 to 6/12), 51% (n=489) were visually impaired with acuity of 6/18 to 6/60, and 41% (n=390) were blind (3/60 to no perception of light - NPL).

Three months after surgery, the distribution had signifcantly shifted such that about 80% (n=764) of all patients achieving a good visual outcome of 6/12 or better (Chi-square = 1026, df = 3, p-value < 0.001). As shown in Table 3.8, post-operative visual acuity was unrelated to pre-operative visual acuity group. In other words, regardless of pre-operative visual acuity, patients ended up with a similar level of visual acuity after surgery.

Table 3.9 Visual acuity in the surgery eye before and 3 months after surgery.

			Visual Acuity at 3 months post-operatively			
Visual acuity on admission	**Number of patients**	**%**	**6/6 - 6/12 n (row %)**	**6/18 - 6/24 n (row %)**	**6/36 - 6/60 n (row %)**	**less than 6/60 n (row %)**
6/ 6 - 6/12	80	8.3%	68 (85%)	9 (11%)	3 (4%)	0 (0)%
6/18 - 6/24	253	26.4%	220 (87%)	23 (9%)	7 (3%)	2 (1%)
6/36 - 6/60	236	24.6%	189 (80%)	31 (13%)	12 (5%)	4 (2%)
less than 6/60	390	40.7%	287 (74%)	46 (12%)	28 (7%)	30 (8%)
All	959	100%	764 (79.7%)	109 (11.4%)	50 (5.2%)	36 (3.8%)

The visual acuity of 866 patients (90.3%) improved by three months after surgery in the sense that they gained at least one Snellen line of acuity after surgery. (Table 3.10) This did not however mean that achieved a "good" visual outcome in terms of their post-operative visual acuity as 20.4% still had a visual acuity of 6/18 or worse (Table 3.9).

Table 3.10 Gain in visual acuity at 3 months after surgery. n=959.

Pre-operative Snellen Acuity (n)	Post-Operative Snellen Visual Acuity (n)									
	6/6	6/9	6/12	6/18	6/24	6/36	6/60	3/60	CF	HM
6/6	3	-	-	-	-	-	-	1	-	-
6/9	16	8	-	3	3	-	-	-	-	-
6/12	16	16	9	2	1	2	-	-	-	-
6/18	52	36	21	11	3	3	3	-	-	-
6/24	42	50	19	7	3	1	-	-	2	-
6/36	38	45	23	13	4	4	2	-	-	-
6/60	32	32	19	10	4	1	5	1	3	-
3/60	8	9	8	2	1	-	5	1	2	-
CF	56	63	37	20	8	3	7	2	11	2
HM	33	52	21	10	4	6	7	2	6	4
All	296	311	157	78	31	20	30	6	24	6

CF - counting fingers
HM - hand movements

Sub-group descriptions of visual outcome

Visual outcome differed significantly by age group. The proportion achieving a good visual acuity declined with age (Chi-square=24.4, df=6, p-value=0.0004). Outcome

was also significantly different between males and females, with fewer females achieving a good visual outcome (Chi-square=8.9, df=3, p-value=0.03). (Table 3.11)

It was likely that the types of pre-operative ocular comorbidity present in these patients could influence visual acuity. As shown in Table 3.11, visual outcome was significantly different in patients with ocular comorbidity (Chi-square=94.4, df=6, p-value <0.00001). 87% (569/651) of patients without ocular comorbidity achieved a good visual outcome, whilst this was the case for only 63.3% (195/308) of patients with ocular comorbidity. 93.3% (n=607/651) of patients without ocular comorbidity gained at least one Snellen line after surgery compared with 84% (n=259/308) of patients with ocular comorbidity.

Table 3.11 Sub-group descriptions of visual outcome at 3 months after surgery.

	Visual Acuity Group - surgery eye at 3 months			
	6/6 to 6/12 n (row%)	6/18 to /624 n (row%)	6/36 to 6/60 n (row%)	less than 6/60 n (row%)
Age Group (yrs) :				
50 to 64	113 (85.6)	8 (6.1)	9 (6.8)	2 (1.5)
65 to 74	426 (83)	52 (10.1)	21 (4.1)	14 (2.7)
>=75	225 (71.7)	49 (15.6)	20 (6.4)	20 (6.4)
All	764	109	50	36
	Chi-square=24.4; df=6; p-value=0.0004			
Sex :				
males	312 (84.1)	37 (10)	13 (3.5)	9 (2.4)
females	450 (76.8)	72 (12.3)	37 (6.3)	27 (4.6)
All	762	109	50	36
	Chi-square=8.9; df=3; p-value=0.03			
Ocular Comorbidity :				
none	569 (87.4)	53 (8.1)	21 (3.2)	8 (1.2)
mild to moderate	129 (69)	29 (15.5)	13 (7)	16 (8.6)
severe	66 (54.5)	27 (22.4)	16 (13.2)	12 (9.9)
All	680	91	41	33
	Chi-square=94.4; df=6; p-value<0.00001			

6.2 Surgically Related Complications

There were 998 records with complete data on surgically related complications at all the specified post-operative periods.

Intra-operative complications

Few patients (n=71, 7%) had some complication during the surgical procedure. The single most frequent complication was rupture of the posterior capsule (n=50). This was not associated with vitreous loss in the majority of these patients (n=39). One patient had a retrobulbar haemorrhage following administration of a retrobulbar local anaesthetic block.

Post-operative complications

Within 24 hours of surgery, 224 (22%) patients experienced a complication, 176 (18%) had a complication reported within one month of surgery (at the first follow-up assessment in the out-patient department); and three months after surgery, 200 (20%) of patients had a complication reported. 11 (1.1%) of all patients experienced some type of complication at all times from the intra-operative period to three months after surgery. The types of complications that occurred at each post-operative period are presented in Table 3.12.

The complications seen in the immediate post-operative period consisted predominantly of corneal oedema and raised intra-ocular pressure, followed by wound leak, iris prolapse, uveitis and hyphaema. It is likely that these events were related to the handling of the eye during the surgical procedure. These gradually resolved, so that the pattern of complications at three months after surgery was quite different. The predominant complication at that time was posterior capsule opacification, followed by raised intra-ocular pressure, clinically detectable cystoid macular oedema and persistent uveitis.

Table 3.12. Post-operative complications of surgery. n = 998.

Type of Complication	Post-Operative Period: Immediate (within 24 hours) n	%	1st Out-patient (within 1 month) n	%	At 3 Months n	%
None	774	77.6	822	82.4	798	80
Corneal oedema	96	9.6	32	3.2	4	0.4
Raised Intra-Ocular Pressure	53	5.3	33	3.3	23	2.3
Wound leak	18	1.8	8	0.8	2	0.2
Iris prolapse	3	0.3	2	0.2	2	0.2
External infection	1	0.1	2	0.2	2	0.2
Endophthalmitis	1	0.1	2	0.2	0	0
Dislocated Intra-Ocular Lens	0	0	0	0	3	0.3
Hyphaema	13	1.3	4	0.4	0	0
Uveitis	14	1.4	21	2.1	11	1.1
Retinal detachment	0	0	0	0	1	0.1
Cystoid macular oedema	0	0	0	0	12	1.2
Soft lens matter	0	0	0	0	3	0.3
Posterior Capsule thickening	0	0	0	0	63	6.3
Other	25	2.5	72	7.2	74	7.4
All	998	100	998	100	998	100

Complications are presented as those that occurred at the specified post-operative period.

Complications at three months are presented by age, sex and presence of pre-operative ocular comorbidity in Table 3.13. No significant differences were observed by age

and sex, but complications were significantly more frequent in the presence of pre-operative ocular comorbidity.

Table 3.13 Sub-group descriptions of surgical complications at 3 months.

	Surgical Complications at 3 months			
	Absent		Present	
	n	(row%)	n	(row%)
Age Group (yrs) :				
50 to 64	102	(77.3)	30	(22.7)
65 to 74	426	(83)	87	(17)
>=75	248	(79)	66	(21)
All	776		183	
	Chi-square=3.4; df=2; p-value=0.18			
Sex :				
males	301	(81.1)	70	(18.9)
females	473	(80.7)	113	(19.3)
All	774		183	
	Chi-square=0.02; df=1; p-value=0.9			
Ocular Comorbidity :				
none	547	(84.0)	104	(16.0)
mild to moderate	138	(73.8)	49	(26.2)
severe	91	(75.2)	30	(24.8)
All	776		183	
	Chi-square=12.8; df=2; p-value=0.002			

The cumulative incidence of the major complications are presented in Table 3.14. The incidence of clinically detectable cystoid macular oedema at 3 months after surgery was 1.2% (n=12). This was associated with good visual acuity of 6/12 or better, in

eight of these patients. Three of these patients with good acuity had posterior capsule rupture during surgery, one of which was associated with vitreous loss.

The incidence of endophthalmitis was 0.3%. All of these cases occurred within one month of surgery. (The definition of endophthalmitis did not distinguish between culture-proven and sterile endophthalmitis). The incidence of retinal detachment within three months of cataract surgery was 0.1% (n=1). This patient had had an extracapsular extraction with a posterior chamber intra-ocular lens implant.

Table 3.14. Cumulative Incidence of the Major Complications. n=998.

Type of Complication	Number with Complication	Cumulative Incidence	95% C.I.
Intra-operative period :			
Capsule rupture	39	3.9%	2.79 to 5.30
Capsule rupture and vitreous loss	11	1.1%	0.56 to 1.96
Within one month :			
External infection	4	0.4%	0.1 to 1.2
Endophthalmitis	3	0.3%	0.07 to 0.87
At three months :			
Dislocated IOL	3	0.3%	0.07 to 0.87
Retinal Detachment	1	0.1%	0.006 to 0.55
Cystoid macular oedema	12	1.2%	0.63 to 2.09
Posterior capsule opacification	63	6.3%	4.89 to 8.0

7. DETERMINANTS OF POOR CLINICAL OUTCOME

Whilst the bivariate analyses provide some indication of the factors that appear to influence clinical outcome, the effect of confounding factors could not be assessed and no quantitative estimate of the adjusted risk of poor clinical outcome could be derived. The determinants of poor visual outcome and those for the occurrence of complications were considered separately using Poisson regression modelling procedures. Full details of these procedures are provided in Appendix A2 and A3.

7.1 Risk Factors for Poor Visual Acuity Outcome

The variables of interest used in the model are presented in Table 3.15. Due to the nature of the complications observed, those at three months after surgery were considered likely to influence visual acuity. Intra-operative complications were also considered as these may influence some of the complications seen at three months, particularly cystoid macular oedema and persistent uveitis.

Univariate analysis had suggested that visual outcome was different amongst sub-groups of patients with and without ocular comorbidity. This was considered first in a Poisson regression model, unadjusted for the effects of any of the other variables. It was found to be a highly significant predictor variable, with increasing risk of poor visual outcome with increasing severity of comorbidity. This model was then extended to include those variables of interest that had complete records : age group, sex, visual acuity on admission in the surgery eye, geographic area, type of hospital, size of ophthalmic unit (given by number of consultants), occurrence of intra-operative complications, complications at three months, capsulotomy indicated, and whether glasses had been dispensed. A stepwise model fitted with these variables identified age of 75 years or over, female sex, the occurrence of complications at 3 months, if a capsulotomy had been indicated and if glasses had not been dispensed by three months

as additional predictors of poor visual outcome, having adjusted for the effects of all the other variables in the model.

Interactions between age, sex, ocular comorbidity and the occurrence of surgically related complications were sought, but none were found to exert any statistically significant effect.

The significant predictive factors identified were fitted on a restricted dataset which now included those with some missing values. Relative risks were obtained. The model was then extended to include the remaining variables of interest (length of stay, type of anaesthetic, grade of surgeon, and waiting time for admission) and a stepwise model performed. No additional significant predictive factors were identified. The estimates for relative risk for the significant predictive factors that had already been identified from the fuller dataset were only slightly affected with the exception of age. The confidence interval around the estimate for the relative risk for age from the restricted dataset included the null value and did not reach statistical significance. This was most likely the result of using a restricted dataset with fewer observations (Appendix A2). The findings of the model from the fuller dataset are reported and presented in Table 3.16.

Increasing severity of ocular comorbidity was associated with increasing risk of poor visual outcome, having adjusted for all the other variables in the model. The presence of mild to moderate ocular comorbidity was associated with a relative risk of poor visual outcome of 1.9 (95% C.I. 1.4 to 2.8), with severe ocular comorbidity having a relative risk of 3.0 (95% C.I. 2.1 to 4.3) . The occurrence of any complication (excluding posterior capsule thickening), at 3 months after surgery was associated with a relative risk for poor visual outcome of 2.0 (95% C.I. 1.5 to 2.8). Patients in whom a capsulotomy was indicated at 3 months after surgery also had a higher risk of poor visual outcome (relative risk 1.7, 95% C.I. 1.1 to 2.6). The older age group of 75 years and over and female sex each had a relative risk for poor visual outcome of 1.4.

The following were not identified as risk factors for poor visual outcome : geographic area, type of hospital, size of ophthalmic department (given by number of consultants), length of stay, type of anaesthetic, grade of surgeon performing the procedure, and visual acuity on admission

Table 3.15 Variables used for Multivariate Analysis for Risk Factors for Poor Visual Outcome.

Variable	Description
Dependent (Outcome) Variable :	
Visual Outcome	Good - visual acuity of 6/12 or better at 3 months Poor - visual acuity less than 6/12 at 3 months
Independent Variables :	
Patient characteristics -	
Age (years)	<75 years , >=75 years
Sex	male or female
Visual Acuity on admission - surgery eye	6/6 to 6/12 6/18 to 6/24 6/36 to 6/60 less than 6/60
Ocular Comorbidity on admission	*None* *Mild to moderate comorbidity:* Drusen or RPE changes at the macula Background diabetic retinopathy *Severe comorbidity :* Disciform macular degeneration Diabetic maculopathy Proliferative diabetic retinopathy Glaucoma Amblyopia
Structure -	
Area	coded 1 to 19
Type of hospital	teaching, specialist eye, or district
Number of consultants in ophthalmic department	<=2, 3, 4 or >4
Surgical Process -	
Length of stay	in-patient or day-case
Type of anaesthetic	general or local
Grade of surgeon performing procedure	Consultant, SR, Reg., SHO, Other
Waiting time for admission	<=6, 7 to 12, >12 months
Intermediate Outcomes -	
Complications at 3 months	present or absent
Capsulotomy indicated at 3 months	yes or no
Glasses dispensed by 3 months	yes or no

Table 3.16 Risk Factors for Poor Visual Acuity Outcome.

Variable	Relative Risk (RR)	95% C.I.	p-value
Age: >=75 years	1.4	1.1 to 1.9	0.017
Sex : Female	1.4	1.05 to 1.9	0.025
Ocular Comorbidity :			
Mild to Moderate	1.9	1.4 to 2.8	<0.001
Severe	3	2.1 to 4.3	<0.001
Other Outcomes :			
Complications at 3 months	2	1.5 to 2.8	<0.001
Capsulotomy indicated at 3 months	1.7	1.1 to 2.6	0.016

Poisson regression model on 957 observations (having adjusted for the other variables in the model - Table 17).

7.2 Risk Factors for Complications

Only complications that were present at three months were considered as these appeared to be different to those occurring earlier in the post-operative period and were more likely to have long term sequelae affecting visual acuity and requiring further care. The predictive variables of interest included in the model are shown in Table 3.17.

Ocular comorbidity was considered first, unadjusted for the effects of the other variables of interest, and was found to be a significant predictive factor though its severity did not influence the estimate for the relative risk. The model was then extended to include the other variables of interest that had complete records, and a

stepwise model performed. No additional significant predictive factors were identified. Interactions between age, sex, ocular comorbidity and the occurrence of complications were sought, but none were found to exert any statistically significant effect (Appendix A3).

Ocular comorbidity was then fitted on a restricted dataset which included those with some missing values, and the relative risks were obtained. The model was then extended to include the remaining variables of interest (length of stay, type of anaesthetic and grade of surgeon) and a stepwise model performed. No additional significant predictive factors were identified. A model was then fitted for ocular comorbidity on this restricted dataset, adjusting for the effect of age, sex, and grade of surgeon performing the operation. These other variables did not demonstrate any significant effect of their own, and the estimates for the relative risk for ocular comorbidity already identified from the fuller dataset were not seen to be affected (Appendix A3). The findings from the fuller dataset are reported and presented in Table 3.18.

Neither the geographic area, the type of hospital , size of ophthalmic department (given by the number of consultants), length of stay, type of anaesthetic, nor the grade of surgeon performing the operation, was observed to influence the occurrence of complications at three months after surgery, in this sample of patients.

Table 3.17 Variables used for Multivariate Analysis for Risk Factors for Complications

Variable	Description
Dependent (Outcome) Variable :	
Complications at 3 months	Present or Absent
Independent variables :	
Patient characteristics -	
Age (years)	<75 years, >=75 years
Sex	male or female
Ocular Comorbidity on admission	*None*
	Mild to moderate :
	Drusen or RPE changes at the macula
	Background diabetic retinopathy
	Severe :
	Disciform macular degeneration
	Diabetic maculopathy
	Proliferative diabetic retinopathy
	Glaucoma
	Amblyopia
Structure -	
Area	coded 1 to 19
Type of hospital	teaching, specialist eye, or district
Number of consultants in ophthalmic department	<=2, 3, 4 or >4
Surgical Process -	
Length of stay	in-patient or day-case
Type of anaesthetic	general or local
Grade of surgeon performing procedure	Consultant, SR, Reg., SHO, Other

Table 3.18 Risk Factors for Surgically Related Complications at 3 months

Variable	Relative Risk (RR)	95% C.I.	p-value
Ocular Comorbidity :			
Mild to Moderate	1.7	1.2 to 2.3	0.004
Severe	1.6	1.04 to 2.3	0.03

Poisson regression model on 957 observations (having adjusted for the other variables in the model - Table 19.)

8. DISCUSSION

8.1 Study Method

8.1.1 Possible Sources of Bias

The biases of particular concern were *selection bias and response bias* that may have been operating during the identification of the sample of patients admitted for surgery. Either could influence the findings and compromise their generalisabilty.

It was unlikely that any selection biases were operating through the *selection of consultants* (at the time of invitation to participate), as all eligible consultants were included in the sampling frame and were invited to participate, and there was no statistically significant difference between those that participated and those that did not (Table 3.1). As consultants were then required to identify and enter their patients into the study, it could have been possible to introduce a bias with respect to *patient selection.* Consultants were given very short notice of the study period and were only informed of the date of the study either on the last working day prior to, or the morning of the first day of, the survey week. This should not have provided sufficient time for consultants to change their admission plans. Although it seemed unlikely that admissions could not have been significantly altered, it was still possible for consultants to select only some (possibly the less complicated cases) of their eligible patients for inclusion in the study. It was not possible to validate the completeness of inclusion of all eligible admissions, and it had to be assumed that little or no selection bias was introduced at this stage. This assumption must be bourne in mind when considering the results.

Another possible source of *selection bias* was the choice of the study week. It was possible that it may have been an atypical week for surgical activity though the findings indicate that this was not so in terms of the "activity" indicators defined for the study. The study week was found to be similar to levels of activity during the preceding months and the previous year.

Whilst it is not possible to exclude all possible sources of selection or response bias, it was considered that no important ones were operating during the study and that a representative sample of cataract patients was obtained from representative settings.

8.1.2 Data Quality

All data should have been collected at the time of admission, during the operation, and during post-operative follow-up. Whether this actually took place in all cases is not known. It was quite possible that some data were obtained retrospectively from the hospital clinical notes after the admission episode or the follow-up assessment, and that their quality or completeness could have introduced *observation bias*.

Overall, most data items were recorded for most patients, with most items being recorded in at least 90% of records. It is possible that where data were missing, the rest of the information on those patients may have been obtained retrospectively from the clinical notes, where some data may have been missing. Post-operative visual acuity in the fellow eye was the single most frequent item not recorded. As it is not the eye of primary interest, information on its acuity is less likely to be routinely recorded in the notes, unless there is a specific reason e.g. it may also need cataract surgery or management for some other condition.

The accuracy (validity and reliabilty) of data recording was probably high as all forms were completed by ophthalmologists. As events of interest were confined to those that were clinically significant, this overcame any problems with interpretation of definitions and it was unlikely that important misclassifications occurred.

It was likely that the level of data completeness that was achieved from the large number of centres was because the data required were of the type that are used and recorded in everyday clinical practice. The findings demonstrate that it is possible for routine clinical data of this sort to be collected in a standardised manner, at a sufficient level of completeness, to provide useful information on surgical practice and clinical outcomes with sufficient detail to allow for case-mix adjustments to be made.

8.2 The Findings

Micro-surgical practice is established with extracapsular cataract extraction and posterior chamber lens implantation being the procedure of choice. This is used routinely and widely offered to patients. A significant proportion of the surgical load (34%), is now devoted to surgery for second eyes. Although the median acuity at listing was 6/36, the implicit threshold at which surgery appeared to be clinically indicated was 6/18 for both first and second eyes. No age or gender differences in visual impairment were observed on admission for surgery. Whilst a small proportion of patients appeared to be admitted for surgery with good visual acuity, it is possible that surgery was indicated for the disability caused by cataract that may not be evident from Snellen acuity measurement alone. This study was not designed to consider these factors, but they are addressed more fully in the following chapters.

The clinical outcomes of cataract surgery have been described. The findings indicate that cataract surgery is generally a clinically safe and effective intervention to improve visual acuity. Cataract surgery was found to be clinically safe in that sight threatening complications such as endophthalmitis and retinal detachment were infrequent events. The cumulative incidence reported for these events were consistent with comparable findings reported at similar post-operative periods.[97][119][120][121] The type of complications observed occurring during the intra-operative and immediate post-operative periods probably reflect handling and instrumentation of the eye during the surgical procedure. Whilst the complications in the immediate post-operative period are common, they are transient and resolve by three months and are not sight threatening. Cystoid macular oedema and persistent uveitis seen at three months are less frequent now compared to their occurrence using older surgical techniques. [97]

The predominant complication three months after surgery was posterior capsule opacification. 6.3% of patients were affected, and in over half a further procedure (e.g. Yag laser capsulotomy) was indicated. Capsule opacification is now recognised as a common complication of modern cataract surgery. It has been estimated that at least 20% of patients are affected up to two years after cataract extraction.[122]. If

left unrecognised and untreated, it may progressively impair vision. Patients need to be informed about the possibility of this complication as many will have been discharged from care before they become symptomatic.

Cataract surgery was found to be clinically effective in that 80% of all patients achieved a good visual outcome of an acuity of 6/12 or better, in the surgery eye, and that 90.3% of patients gained at least one Snellen line of acuity three months after surgery. It has been suggested that when change in visual acuity is considered over a relatively short period of time (7 weeks), then at least two lines of acuity, as measured by high contrast letter charts such as the Snellen chart, should be considered to constitute a statistically significant change in performance during routine follow-up of patients.[123] Using this criterion, 82% of patients gained at least two lines of Snellen acuity by three months after surgery. However, since the assessment of change in visual acuity in this study was made after a specific, and acute intervention, and that the time interval at which this was made was much longer (3 months), it was considered that a change in one line of Snellen acuity was likely to constitute a clinically important change when compared to the pre-operative acuity. Given the reliabilty of measuring *uncorrected* Snellen acuity *at any one time*, a real change in *uncorrected* acuity has been reported to constitute a doubling of the minimum visual angle.[87] In this study *best* corrected visual acuity was measured. Consequently it was possible that the reliability of measuring corrected Snellen visual acuity and that which constitutes a real change in acuity at separate occasions (before and three months after surgery), was at least the same as, or perhaps likely to better than that reported for measuring uncorrected Snellen acuity at any one time. Thus a change of one Snellen line of acuity three months after surgery as compared to pre-operative values, was considered likely to represent a clinically important change post-operatively.

Outcome was not seen to be influenced by several measures of health care provision including grade of surgeon, type of hospital, size of unit, geographic area, length of stay or type of anaesthetic used. With a two-sided alpha error set at 0.05, the study had a power of 90% to detect a relative risk of 1.5 for poor outcome associated with

these factors. [124] Whilst it was possible that some smaller differences may have occurred and were not detected, it was unlikely that such small changes were of any practical significance. The predictive factors for poor clinical outcome that were identified, were not unexpected, except perhaps for age and sex which were identified as predictive factors for poor visual outcome. No adequate explanation was found for the observed risk of poor visual outcome associated with females and age 75 years and over, the estimates for their relative risks having been adjusted for the other variables in the model. Ocular comorbidity is an important predictive factor for both visual outcome and complications. As about a third of patients have some comorbid condition, quantification of the risk allows for patients to be better informed of the outcome of surgery they can expect, and for planning their post-operative management.

Overall the findings provide previously unavailable information on the clinical outcomes associated with established micro-surgical cataract extraction and posterior chamber intraocular lens implantation, that are achieved in routine clinical practice in the UK.

Advances in surgical technique and intraocular lens technology have been aimed principally at providing better post-operative visual rehabilitation and quality of vision. Whilst the less frequent occurrence of complications is likely to be a direct consequence of these developments, the impact of such changes on visual acuity is not as evident. The level of visual outcome currently achieved is about the same as that described over the last twenty years or so with less refined surgical techniques or during changing surgical practice, confirming that a cataract extraction (by any means) will improve visual acuity. This is not surprising for two main reasons. First, the burden of ocular comorbidity in cataract patients, which may influence visual outcome, is unlikely to have changed significantly over this time period. Second, visual outcome has only been assessed in terms of visual acuity (Snellen or its equivalent), measured in a clinical setting. Measurement of visual acuity by this means and in standard clinical settings does not reflect any improvement in the quality of the image or the quality of visual acuity and vision, that is provided by intraocular lenses (e.g. by the absence of

associated optical aberrations and negligible image magnification) and any influence that this improved quality of vision may have on visual functioning, and perhaps health related quality of life. This is considered in the following chapters.

9. SUMMARY OF FINDINGS

The main findings from this study may be summarised as follows :

- A representative sample of patients having surgery for age related cataract was obtained from representative settings in the UK.

- Data collection was 90% complete

- Current clinical practice was described, confirming that microsurgical techniques for cataract extraction and posterior chamber intraocular lens implantation were procedures of choice and widely available.

- Second eye surgery constitutes a significant proportion of the cataract surgical workload.

- Cataract surgery was observed to be clinically effective in improving visual acuity in the eye that had surgery, with 80% of patients achieving a good visual acuity outcome.

- Cataract surgery was observed to be clinically safe in that most of the complications occurring after surgery were transient, resolving within 3 months, and sight threatening complications were infrequent events.

- Risk factors for poor clinical outcome were identified and quantified. These were patient-related factors, principally ocular comorbidity.

- Measures of health care provision were not found to be associated with poor clinical outcome.

Chapter 4

THE CATARACT OUTCOME STUDY : METHODS

1. INTRODUCTION

The next five chapters (chapters 4 to 8) are concerned with patient perceived measures for the outcome of cataract surgery and their relationships with clinical measures, particularly visual acuity. A prospective cohort study of the impact of surgery on these measures in the context of the overall care provided was conducted - the Cataract Outcome Study. The main patient perceived measures used in this study were:

i. visual function - this term refers to functioning in everyday activities that require vision

ii. quality of life

iii. vision-related quality of life

The following approach was taken for their assessment and measurement :

- A disease specific measure of functional status (disability) was used. This was the VF-14, a functional index for vision related activities

- A generic measure was used for health-related quality of life (handicap) This was the Sickness Impact Profile (SIP).

- A modified generic measure was used as a disease-specific measure for vision-related quality of life (handicap) - the Vision-Related -SIP.

The objectives of the Cataract Outcome Study were :

1. to describe and quantify the impact of cataract on visual acuity, visual function, and quality of life and their inter-relationships.

2. to describe and quantify the short term (at 4 months) and medium term (at 12 months) outcomes of cataract surgery in terms of visual function and quality of life and their inter-relationships.

2. STUDY DESIGN

This was a prospective, observational cohort study of patients admitted for their first cataract extraction within the NHS. It was conducted in three district general hospitals in two outer London districts in North Thames Region. All six consultants at the participating hospitals had agreed to take part in the study and to provide clinical data and access to their patients. The recruitment period for the study was from May 1994 to August 1995. All patients were followed up for short term outcome at 4 months after surgery, and at 12 months after surgery for medium term outcomes. Some patients in the cohort were expected to have had surgery to the second eye during their 12 month follow-up.

Ethical approval from the appropriate district ethics committees was obtained. All patients received an explanation (verbal and written) about the objectives of the study and what would be required of them if they agreed to participate. Patients were required to provide written consent for their agreement to participate, prior to recruitment and entry into the study.

The study centre was the Royal College of Ophthalmologists, London.

3. SAMPLE SELECTION

3.1 Centre Selection

From the National Cataract Surgery Study, no significant associations were observed between clinical outcome and type of hospital, number of consultants in an eye unit , or by geographic area. Subsequently, the locations for the study were selected for the following reasons :

- The hospitals selected provided a surgical service for cataract for an urban, suburban and rural populations

- The hospitals were typical in that they were district general hospitals

- The hospitals were of typical size in terms of the number of consultants in the department (n=3).

- North Thames Region was selected for the location of the study primarily for its proximity to the study centre thus facilitating administration of the study.

3.2 Patient Selection

All patients of 50 years of age and over that were to be admitted for surgery for age-related cataract to their first eye, during the recruitment period, were eligible for inclusion. Patients being admitted for second eye surgery and those patients having surgery for other types of cataract or combined procedures were not eligible for inclusion.

All patients that had planned admissions for cataract surgery during the recruitment period were identified by the admissions departments of the participating hospitals. Those patients that were to be admitted for first eye surgery were sent a letter telling them about the study with an invitation to respond if they would be interested in taking part (provided in Appendix B1). This was included with the routine admission correspondence which required a response regarding their availability for the proposed date of surgery.

Patients who agreed to take part were then contacted by the study interviewer assigned to each district. At this time the interviewer was able to answer any queries that arose, and an appointment for the interviewer to visit the patient at home (before their

pre-assessment and admission), was then arranged. At this first home visit the interviewer was required to obtain written consent from the patient before recruiting patients into the study and conducting the baseline pre-operative interview.

The sample obtained was compared with a sample of at least equivalent size of the non-participating eligible patients, and the national sample from the National Cataract Surgery Study in terms of age and sex.

4. SAMPLE SIZE

The outcomes considered for sample size calculation were the patient perceived outcomes of visual function (VF-14) and quality of life (SIP and VR-SIP). Sample size was calculated to detect a specified level of difference δ_T (effect size), in visual function and quality of life scores before and after surgery to the first eye, and between first and second eyes, , where $\delta_T = \mu_0 - \mu_1 / \sigma$. [125] ($\mu_0$ is the mean score before surgery and μ_1 is the mean score after surgery at the specified time, and σ is the standard deviation of the scores before surgery. It has been suggested that δ_T=0.2 constitutes a small difference; $\delta_T = 0.5$ a moderate difference and $\delta_T = 0.8$ a large difference.[125]

Sample size was calculated based on a paired t-test, using stringent criteria (δ_T set at 0.2) to detect a small difference in first eyes before and after surgery in patient perceived outcomes, with a two-sided alpha set at 0.05. A sample of 264 patients would have 90% power to meet these criteria, and a sample of 326 patients would have a power of 95%.

For the outcome after second eye surgery, it was sufficient to detect a moderate difference in visual function and quality of life between surgery to the first, and subsequently the second eye, as it was possible that a small difference may not be distinguishable from the impact of surgery to the first eye. Sample size calculations

were based on an un-paired t-test, with δ_T set at 0.5, a two-sided alpha set at 0.05. A sample of 85 patients in each group (first eye only and both eyes) would have 90% power to meet these criteria.

5. CONDUCT OF THE STUDY

Throughout the study, data collection was in two parts : clinical data and a patient interview. All clinical data were collected in a standardised manner on specific forms by ophthalmologists, and all interviews were conducted by trained interviewers. An interviewer-administered approach was chosen as, at least pre-operatively, patients were likely to be visually impaired, and this might have posed problems with self administration. In addition, the length of the interview might have caused difficulties for self-completion.

All data were returned to the study centre and held on a customised database using the Paradox 4.5 software, and all data were held in accordance with the Data Protection Act 1984.

5.1 Clinical Data

Before the study started, workshops were held at each hospital. All medical, nursing , clerical and administrative staff who were likely to be involved in the study were invited to attend. The objectives and the protocol for the study were presented and practical aspects of patient recruitment and follow-up that may be encountered during the conduct of the study were discussed. Contact personnel and phone numbers were also provided to ensure direct access and communication with study investigators.

One consultant at each unit was identified as a local co-ordinator to take responsibility for the unit's overall participation and commitment, to supervise data collection and to facilitate communication between the unit and the investigators regarding progress of

the study and to facilitate the organisation of follow-up after surgery. The local co-ordinator was provided with feedback on a monthly basis on patient recruitment and data collection (e.g. completion, outstanding forms not returned to the study centre). In addition meetings were held with the principal investigator, every two months to discuss any issues arising .

Clinical data based on the National Cataract Surgery Study were collected. The main items included :

Pre-operatively -

age

sex

best corrected visual acuity in each eye

clinically evident ocular comorbidity

history of medical comorbidity

type of surgical procedure

Peri-operatively and post-operatively (within 48 hours) -

the occurrence of complications :

capsule rupture with and without vitreous loss

endophthalmitis

Post-operatively (at 4 and 12 months) -

best corrected visual acuity in each eye

the occurrence of complications :

cystoid macular oedema

posterior capsule opacification

retinal detachment

The full booklet of forms is provided in Appendix B2. Baseline pre-operative data were collected at the pre-assessment clinic, which was up to two weeks prior to surgery. The 4 month clinical follow-up was incorporated within the routine follow-

up arrangements for patients in the out-patient clinic. However, dedicated follow-up clinics were held for the 12 month clinical assessment, as this was not part of the routine post-operative management, unless specifically indicated.

5.2 Patient Interview

An interviewer was appointed for each district. This interviewer conducted all the interviews in his/her district. All the interviews (pre-operative, at 4 months and at 12 months), were conducted at the patients' homes and were arranged by the interviewer. Training sessions were held for both interviewers together to standardise the administration of the interview. This also included instruction on dealing with additional explanations of questions that may be required before eliciting a response from the patient. Monthly meetings were held to review progress with recruitment and follow-up. The interviews contained several patient perceived measures and took about 45 minutes to administer. These measures included the following :

a visual function index - the VF-14
a generic quality of life instrument - The Sickness Impact Profile (SIP)
a modified generic quality of life instrument - Vision-Related-SIP (VR-SIP)
global measures of visual health
global measures of health
a cataract symptom scale
a comorbidity "bothersome" scale

The complete interview is provided in Appendix B3. The interview was administered in a standardised manner. It was appreciated that whilst the interview was comprehensive, this also meant that it was long. If, despite an explanation about their involvement in the study, patients felt that they could not or did not want to complete the entire interview, the interview was terminated at a standardised stage. This was half way through the interview and represented a natural break. The first half was related to vision and general health, and the second half was concerned with quality of life (SIP and VR-SIP).

6. INSTRUMENTS FOR THE ASSESSMENT OF THE IMPACT OF CATARACT SURGERY

6.1 Clinical Measure of Impairment : Visual Acuity

As mentioned in Chapter 1, vision is made up of both optical and neural components. Visual acuity is probably the most significant measure of the functional integrity of the eye. All types of cataract, if sufficiently advanced, interfere with vision through their basic effect on the optical system of the eye, by causing light scattering. Although visual acuity receives the most attention in cataract, other aspects of the optical and neural functioning of the eye may also be affected and contribute to the overall effect on vision. These include contrast sensitivity, colour vision, visual field, binocularity and stereopsis. Although the symptoms of cataract quite often relate to these aspects of vision, unlike visual acuity, they are not routinely assessed in the management of patients with cataract.

Visual acuity is regarded as an indicator of overall visual performance and as such, may be reasonably expected to be associated with "visual functioning" in the sense of the ability to perform vision-dependent tasks or activities.

In this study, the purpose of measuring visual acuity was :

- to describe the overall visual outcome of cataract surgery i.e. the impact of surgery on the visual acuity of the affected eye.

- to describe and examine the relationship between visual acuity and the patient-perceived outcomes of visual function (VF-14) and quality of life (SIP and VR-SIP).

- to identify the appropriate measure of visual acuity that is associated with visual performance in everyday activities.

6.1.1. Measurement of Visual Acuity

Visual acuity was measured by the Snellen Test Type. Whilst being aware of some of the limitations with this test type,[81][82][83] it was chosen because it is a universally recognised test of visual acuity, it enjoys legal status, and is the "standard" by which ophthalmologists judge and are judged. It is routinely used in clinical practice, it is widely available, and medical and nursing staff of ophthalmology departments are familiar with its use, recording and interpretation of the measurement. The standard back-illuminated Snellen optotype, conforming to British Standard 4274:1968, [126] was used.

Other types of high contrast acuity charts have been proposed as being more suitable for research purposes [84][85][86], but they are not routinely available in ophthalmic departments, and their use and the interpretation of the logMAR acuity provided is not as familiar to all staff involved in the care and assessment of routine cataract patients.

6.1.2. Which Eye ?

Visual acuity is usually assessed unaided and best corrected (wearing glasses if worn, or with pin-hole or after refraction) for each eye, separately. Binocular visual acuity, assessed with both eyes simultaneously, taking account of the input from each eye, is not routinely assessed. When visual performance in both eyes are equal, binocular performance has been shown to be superior to that of the monocular - a phenomenon referred to as binocular summation [127.] When the two eyes are not equal, binocular performance is lower than that for the better eye - a phenomenon referred to as binocular inhibition. [128-135]

Whilst this may not affect the clinical outcome of cataract surgery assessed by the change in post-operative visual acuity in the surgery eye, it may be more important when considering the relationship between visual acuity and visual functioning (ability to perform vision-dependent activities) and quality of life. The best acuity in the better eye has been conventionally regarded as indicating the visual acuity that influences the individual's functioning in everyday activities. However this does not take account of

the individual contribution from each eye and the influence that this has on binocular vision.

In the study, visual acuity was recorded for each eye (the surgery eye and the fellow eye), both unaided and best corrected. It was measured pre-operatively, and at 4 months and 12 months after surgery. As the visual acuity in the fellow eye is not routinely measured and recorded in practice (especially after surgery), the need to do so was highlighted in the training workshops with clinical staff. The possibility of recording binocular visual acuity was also raised with the clinicians, but was abandoned because it was felt to be too far removed from routine practice and would therefore suffer from poor compliance and compromise data quality.

6.2 The VF-14 - An Index of Visual Functioning :

A Disease-Specific Patient Perceived Measure of Disability

The VF-14 is a new instrument designed to provide a specific measure of functioning (visual functioning) in cataract patients.[136] It contains 14 items which include a broad spectrum of vision-dependent activities performed in everyday life that may be affected by cataract. It has been used for the first time in the UK in this study.

6.2.1. Development of the VF-14

The instrument was developed by the Cataract-PORT Team based at Johns Hopkins University. Although it was designed to provide a patient-oriented assessment of the impact of cataract and cataract surgery on visual functioning, its origins were based in clinical practice and clinical experience.

Initially, relevant items (based on clinical observations in practice) were identified by the ophthalmologists on the team. These were based on the functional symptoms they commonly ascertained from patients in routine practice when assessing a patient for

cataract surgery. In addition the team reviewed vision-dependent tasks in other instruments assessing functional status and vision-research questionnaires[103][137][138], to identify any functional activities that might be affected by cataract, for inclusion in the initial list. This list was then reviewed by an expert national advisory panel (Cataract-PORT Study), which was composed of ophthalmologists and optometrists. The panel were asked to ensure that : the list contained the full spectrum of functional limitations experienced by cataract patients; to exclude or combine any items that may constitute functionally equivalent tasks with respect to vision; and to specify relevant functional activities that had not yet been identified.[136]. Following this process, the final instrument contained 14 items.

6.2.2. Content and Administration of the VF-14

The full instrument is presented in Appendix B3. The range of activities encompass all possible aspects of vision :

- near vision : e.g. reading small print (labels etc.), reading a book or newspaper, sewing, carpentry, writing letters/ filling out forms
- intermediate : e.g. watching TV, seeing steps/kerbs, cooking
- distance vision : e.g. reading street / shop / traffic signs, recognising people close by, sports, driving

The 14 items addressed by the index were assessed by 18 questions. For each of the 12 items not related directly to driving, patients were asked whether, even with their most recent glasses, they had any difficulty in doing the activity. The responses allowed were “yes”, “no”, or “do not do that activity for reasons unrelated to vision”. For each activity for which patients responded to as “yes”, they were asked how much difficulty they currently had with that activity - “a little”, “moderate amount”, “great deal” or “unable to do”, because of their vision. The last two items in the index were concerned with difficulties with day-time and night-time driving and were asked in a

slightly different fashion to take account of current drivers and those patients who either did not currently drive or had never driven.

The VF-14 was contained in the patient interview and was administered by trained interviewers pre-operatively and at 4 and 12 months after surgery.

6.2.3 Scoring of the VF-14

For each of the items addressed in this index, a score of 4 was assigned when patients reported "no difficulty" with the activity; a score of 3, 2 or 1, when patients reported "a little", "a moderate amount", or "a great deal" of difficulty, respectively, with the activity, and a score of 0 when patients were "unable to do" that activity because of their vision. The score is based on applicable items and the amount of reported difficulty experienced in performing those activities. An item was not included in the scoring if patients did not do that activity for a reason other than their vision e.g. if patients had never taken part in sports or if they never cooked for themselves . No minimum number of applicable items was required.

Scores on all activities that the patients performed or did not perform because of their vision were then averaged, producing an average score between 0 and 4. This average score was multiplied by 25 to provide a possible final score ranging from 0 (unable to do all applicable activities because of vision) and a maximum of 100 (able to do all applicable items without difficulty).

The purpose of measuring visual function using the VF-14 was to :

- describe and quantify the impact of cataract and surgery on visual function
- to describe and examine the relationship between visual function and visual acuity and quality of life.
- to assess its contribution to measuring the outcome of cataract surgery

6.3 Global measures of vision :

Disease-Specific Patient Perceived Measure of Disability

Patients were asked two general questions regarding their vision. The first related to the overall amount of trouble they were having with their vision. The response options were "none", "a little", "a moderate amount ", or "a great deal". The second question related to the overall satisfaction of the patients with their vision. The response options were "very dissatisfied", "moderately dissatisfied", "moderately satisfied", or "very satisfied". (Appendix B3)

6.4 Global measures of health :

Generic Patient Perceived Measure of Disability

Patients were asked two questions regarding their general health. The first related to their rating of their general health. The response options were : "excellent", "very good", "good", "fair", or "poor". The second question related to their assessment of their general health compared to other people their own age. The response options were : "much better", "somewhat better", "about the same", "somewhat worse", or "much worse". (Appendix B3)

6.5 The Sickness Impact Profile :

A Generic Measure of Health-Related Quality of Life - Handicap

The Sickness Impact Profile (SIP) was used to assess the quality of life of patients having cataract surgery. It has not been used before on cataract patients in the UK. It was selected for this study in preference to the UK version of the SIP (the FLP), [149] to allow for consistency with a similar study carried out in the USA. The SIP is also a well established generic measure of health status and quality of life, which has been

extensively evaluated, validated and widely used. [63][136][139 - 148]. A copy is provided in the Appendix B3.

6.5.1. Background and Development of the SIP

The SIP was developed as a measure of patient perceived health-related quality of life, for use as an outcome measure for health care evaluation across a wide range of health problems and diseases, across socio-demographic and cultural sub-groups. It was designed to be sensitive to change or differences in health-related quality of life that occur over time or between groups and was intended for use in measuring outcomes of health care.[63[64]

Sickness is measured in relation to its impact on behaviour. The profile emphasises sickness-related dysfunction (impact of sickness on daily activities and behaviour) as such reports can be verified by observation and can be obtained whether or not a patient is receiving care. The items included in the SIP focus upon changes in performance rather than capacity i.e. they are concerned with what a person does or does not do, rather than with what they can or cannot do.

The instrument was developed on the basis of a literature review, statements collected from health professionals, and interviews with healthy and ill people which described "sickness related dysfunction". Following a succession of field trials the final version contained 136 items referring to illness-related dysfunction in 12 categories : work, recreation and pastimes, emotional behaviour, alertness behaviour, home management, sleep and rest, eating, body care and management, ambulation, mobility, communication and social interaction.[64] Only those statements which apply to respondents on the day of completion and are related to their health are endorsed.

6.5.2 Reliability and Validity of the SIP

The reliability and validity of the SIP have been evaluated and described in detail [64] and are summarised here.

Regarding reliability, the SIP has high internal consistency (r=0.94) and high test-retest reliability (r=0.92). Reliability in these terms was also high when considered by mode of administration of the SIP : test-retest reliability r=0.97 for interviewer administered, r=0.87 for self-administration; and internal consistency was similar for both modes of administration (r=0.94). Criterion validity and convergent and discriminant validity of the SIP were moderate to high and in the direction hypothesised.[64] These were all tested in the USA. It had to be assumed that the validity and reliability in the UK would also be satisfactory, as no testing as has been reported.

6.5.3. Scoring of the SIP

The responses can be summarised by an overall score, by physical and psychosocial dimension scores or by category scores. All scores range from 0 to 100. The lower the score the better the respondents' health status. A score of 0 indicates no reported dysfunction and as score of 100 severe dysfunction.

The score for the SIP may be calculated using item weights that indicate the relative severity of limitation implied by each statement.[64][139] The overall score is calculated by adding the scale values for each item checked across all categories and dividing by the maximum possible dysfunction score for the SIP. This figure is then multiplied by 100 to obtain the overall SIP score. The two dimension scores are calculated using a similar formula but limiting the calculations to the relevant items : ambulation, body care and management, and mobility for the physical dimension score; and social interaction, alertness behaviour, emotional behaviour and communication for the psychosocial dimension score. The remaining categories - sleep and rest, eating, work, home management and recreation and pastimes - are each calculated separately as independent category scores.

6.6 Vision-Related Sickness Impact Profile (VR-SIP) :

A Disease Specific (Modified Generic) Measure of Vision-Related Quality of Life - Handicap

The Vision-Related SIP (VR-SIP) represents a modification of the generic SIP (see Appendix B3). It was developed by the Cataract PORT team at Johns Hopkins University. Its purposes were to quantify how much of their general dysfunction and quality of life patients attributed to their vision i.e. provide a measure of vision-related quality of life, and to improve the sensitivity of the SIP. Each time patients responded positively to an item contained in the SIP, they were asked whether they thought the statement applied because of their vision. Responses to the latter questions were used to calculate a Vision-Related SIP score in the same manner as for SIP, providing an overall score, two dimension scores and category scores. This modification has previously only been used on a sample of cataract patients in the U.S. This is its first use in the UK.

The purpose of using the SIP and VR-SIP was :

- to describe the impact of cataract and surgery on health and vision-related quality of life.

- to describe and examine the relationship between health and vision-related quality of life and visual acuity and visual function.

- to assess their contribution to measuring the outcome of cataract surgery

6.7 Cataract symptom "bother" score :

A Disease Specific Measure - Handicap

Patients were asked about whether they were bothered by any of five symptoms that are commonly reported by patients with cataract. These included : double or distorted vision; seeing glare, halo or rings around light; blurry vision; colours looking different than they used to in a way that is disturbing ; and worsening of vision within the past month. If the patient was bothered by a symptom, a score of 1 was assigned to it, and a score zero if the patient was not bothered by that symptom. The sum of the scores for all five symptoms was then multiplied by 20 to provide a cataract symptom score ranging from 0 (not bothered by any of the symptoms), to 100 (bothered by all five of the symptoms).

The full symptom scale is provided in Appendix B3.

6.8. Comorbidity "bothersome" score : A Generic Measure - Handicap

Patients were also asked whether they had any of 29 medical symptoms or conditions derived in part from the list of illnesses in the Functional Assessment Inventory [150] and, if they did, how much each interfered with their activities ("not at all", "a little", or "a great deal"). For each symptom or condition, a score of 0 was assigned if the patient did not have the symptom or condition. A score of 1,2, or 3, was assigned if the patient had the symptom or condition and was either "not bothered by it", was bothered "a little" by it, or was bothered "a great deal" by it, respectively. Scores on the 29 items were summed yielding possible medical comorbidity bothersome scores ranging from 0 to 87.

The complete scale is provided in Appendix B3.

7. STATISTICAL METHODS

7.1 Introductory Notes

The descriptive findings regarding the characteristics of the study sample and the clinical outcomes are reported first. Where appropriate, the 95% confidence intervals are provided for the estimates obtained. For proportions, these were calculated by the normal approximation to the binomial distribution for large proportions and by the exact method for smaller ones.[116] For continuous variables the un-paired t-test was used to test the significance of an observed difference between the mean values of different groups or sub-groups. For comparing patients before and after surgery the paired t-test was used. For categorical variables the Chi-square test was used to determine whether the observed differences in proportions between sub-groups was statistically different.

The methods of analysis for the main outcome measures of interest (visual acuity, visual function, health- and vision-related quality of life) and their relationships are described in the following sections. All analyses were performed using SPSS 6.1 for Windows [151 - 153].

7.2 Clinical Measure : Visual Acuity

Snellen visual acuity was treated both as a continuous variable and as a categorical variable when grouped according to level of acuity. The visual acuity groups were defined as :

6/6 to 6/12	:	good visual acuity
6/18 to 6/24	:	moderate visual impairment
6/36 to 6/60	:	severe visual impairment
less than 6/60	:	blind.

A Snellen acuity of 6/12 is the minimum legal requirement for a driving licence in the UK. Acuity of 6/6 to 6/12 is thus regarded as "good" visual acuity. The visual acuity groups took into consideration the reliability of measuring acuity, at any one time, using the Snellen (or equivalent high contrast) test types,[87] and the limitations of this chart for measuring very good or very poor levels of visual acuity [81][82][83].

Visual acuity was considered in terms of the :

a. Surgery eye visual acuity - the best corrected visual acuity in the eye that had surgery before and after surgery

b. Better eye visual acuity - the best corrected visual acuity in the patient's better eye . Pre-operatively this was most likely to be the fellow eye, but could possibly be the surgery eye in some cases. Post-operatively this was most likely to be the surgery eye.

c. Person Visual Acuity (VP) Score - this represents an attempt to take account of the visual acuity input from both eyes and is described below.

7.2.1 Calculation of the VP Score and VP%

To calculate the VP score, the monocular visual acuity from each eye was first grouped as follows :

6/6 to 6/9	=	1
6/12 to 6/18	=	2
6/24 to 6/36	=	3
6/60	=	4
< 6/60	=	5

The groups in this case were distinguished by two Snellen lines of acuity up to 6/36 and then acuities of 6/60 and less than 6/60 constituted separate groups[81][82][83][87]. A score matrix was then produced as shown in Table 4.1. for all fifteen possible, distinct combinations of visual acuities ranging from 0 to 14, based on this grouping.

Table 4.1 Matrix of Possible Combinations of Grouped Visual Acuities from Both Eyes

VP SCORES

		Right Eye Visual Acuity				
		6/6 to 6/9	**6/12 to 6/18**	**6/24 to 6/60**	**6/60**	**less than 6/60**
Left Eye Visual Acuity		**1**	**2**	**3**	**4**	**5**
6/6 to 6/9	**: 1**	**14**	13	12	11	10
6/12 to 6/18	**: 2**	13	**9**	8	7	6
6/24 to 6/36	**: 3**	12	8	**5**	4	3
6/60	**: 4**	11	7	4	**2**	1
less than 6/60	**: 5**	10	6	5	1	**0**

Highlighted cells (14,9,5,2,0) within the table represent equal visual acuities in each eye

Each combination (VP score) was then scaled to a maximum score of 100, calculated as follows:

$$VP\ \% = (VP/14)] \times 100$$

A maximum score of 100 represented equal vision of 6/6 in both eyes and a minimum score of 0 represented bilateral blindness. This score reflected not only the visual acuity in each eye but also the disparity between the two eyes. It corresponded to a

weighting of about 75% to the eye with better acuity. For example, taking extreme visual acuities of 6/6 in one eye and blind in the fellow eye, corresponds to a combined VP score of 10 (Table 4.1), and a VP% of 72. This approach was consistent with other reported methods for combining the visual acuities of both eyes to arrive at a visual acuity score for the person. [154][155][156]

7.2.2 Associations between measures of visual acuity

In order to identify which measure of visual acuity (surgery eye, better eye, VP score) would be the most appropriate indicator of visual performance influencing visual function (ability to perform vision-dependent activities and tasks) and quality of life, bivariate correlations (Pearson and Spearman) were first made between surgery eye acuity , better eye acuity and VP score, both before and after surgery. Next, associations between measures of visual acuity and measures of visual function and health- and vision-related quality of life were investigated by means of bivariate correlations.

7.3 Patient Perceived Measures : VF-14, SIP, VR-SIP

The VF-14 provided a score of visual functioning ranging from 0 (greatest dysfunction) to 100 (no reported dysfunction). Both the actual score (either pre- or post-operatively) and the change in score post-operatively, were continuous variables and were treated as such in all analyses.

The SIP and VR-SIP each provided an overall score, dimension scores and twelve category scores ranging from 0 to 100. These scores were continuous variables and were treated as such in all analyses.

The relationships between visual acuity, visual function and health and vision-related quality of life were examined pre-operatively using the actual visual acuity and actual scores for visual function and quality of life; and post-operatively with the change in visual acuity and change in score.

The change in score, rather than the absolute score achieved after surgery, was preferred for analysis of post-operative data as it represents the impact of cataract surgery on visual acuity, visual function, health and vision-related quality of life. The VF-14, SIP and VR-SIP each provide a finite, maximum achievable score of 100, and the maximum achievable Snellen visual acuity was 6/6. The actual score or visual acuity achieved after surgery represents the level of performance at that time, and does not provide any indication of the gain (or loss) achieved from pre-operative levels. As it is highly unlikely that all patients would have the same, or similar levels, of visual acuity, visual functioning or quality of life pre-operatively, they would therefore have different capacities for gain or loss as a result of surgery. The actual post-operative score or acuity does not take this into account, nor does the change in score or change in acuity per se. Therefore the change in score or acuity was adjusted for by the pre-operative values, thereby providing a better indication of the effect of cataract surgery on acuity, visual function or quality of life. (This is discussed in detail later in 7.3.7).

7.3.1 Reliability and Validity of the VF-14

The VF-14 is a new instrument. Aspects of the reliability and validity of the VF-14 have been reported for a sample of cataract patients in the U.S.[136] We have used the VF-14 for the first time on cataract patients in the UK and performed an independent assessment of these characteristics for this instrument. Reliability and validity was assessed using the pre-operative VF-14 score.

The reliability of the VF-14 was only assessed in terms of its internal consistency. It was expected that the items should be modestly correlated with one another and that each item should correlate with the total score. This was done by computing

Cronbach's alpha. Cronbach's alpha is a reliability coefficient based on the internal consistency of a test. It is an inter-item correlation statistic and is based on the average correlation of items within the test. It can be interpreted as correlation coefficient with a value ranging from 0 to 1. [153]

The validity of the VF-14 was considered in terms of content validity and criterion validity.

Content Validity - The final instrument containing 14 items was produced following a review by an expert national advisory panel composed of ophthalmologists and optometrists to ensure that : the list contained the full spectrum of functional limitations experienced by cataract patients; to exclude or combine any items that may constitute functionally equivalent task with respect to vision; and to specify relevant functional activities that had not yet been identified.[136] In doing so, this exclusively professional and clinical expert panel assessed the content validity of the instrument.

Criterion Validity - Since the VF-14 is an index of visual functioning, the basic a priori assumption was that it should have some, though not necessarily a close relationship with visual acuity. Criterion validity was assessed by examining the correlation between the pre-operative VF-14 scores and several other measures of vision. These included visual acuity on admission and global self rating of function for the overall amount of difficulty and satisfaction patients had with their vision. Correlation with quality of life was also examined.

7.3.2. Reliability and Validity of the SIP and VR-SIP :

Whilst it was assumed that the reported validity and reliability of the SIP would also apply to UK patients, neither the SIP nor the VR-SIP have been used in the UK for cataract patients.

Their criterion validity was assessed by using their pre-operative scores. In the case of SIP, the assumption was that it should have some relationship with measures of health.

This involved an examination of the correlation between the pre-operative scores and other measures of health : global self rating of health and the comorbidity "bothersome" score. In the case of VR-SIP, the assumption was that it should have some relationship with visual health. This involved an examination of the correlation between the pre-operative scores and other measures of visual health : visual acuity, VF-14 scores, and global self rating of vision.

7.3.3 Description of Scores :

Pre-operatively and at 4 and 12 months after surgery

Descriptive summaries of all scores (pre-operative and post-operative scores, and change in scores post-operatively) are presented first for each time period. These are described in terms of their means with standard deviation and 95% confidence intervals; the median and inter-quartile range; and the minimum and maximum values.

Crude (unadjusted) relationships between pre-operative score, or change in score, and continuous variables of interest (pre-operatively and post-operatively) were then examined. First, scatterplots and Pearson and Spearman (non-parametric) correlation coefficients indicate whether an association exists or not for criterion validity. Simple linear regression with pre-operative score or change in score, as the dependent variable and any one of the other variables of interest, in turn, provide regression coefficients to describe the strength of this association. Diagnostic plots for the validity of these regressions were also examined.

Absolute scores and change in scores, within sub-groups of categorical variables were then considered. The mean scores (s.d. and 95% confidence intervals) and median score (with inter-quartile range) within each sub-group are presented. The means were compared either by a t-test for comparison of two groups; or by a one-way analysis of variance using the Bonferroni test of significance for multiple comparisons, with the level of significance set at 0.05.[151] Where the Levene test for homogeneity indicated that the assumption of equal variances was not held for a one-way analysis of

variance, the non-parametric Kruskal-Wallis test was used. This is a non-parametric alternative to a one-way analysis of variance.

7.3.4 Determinants of Pre-operative Scores : VF-14, SIP and VR-SIP

Independent factors that may influence pre-operative score (VF-14, SIP and VR-SIP) were considered in separate multiple regression models. The models provided regression coefficients (partial regression coefficients in the case of pre-operative VF-14 scores), which indicate how much the value of the dependent variable changes when the value of the independent variable increases by one unit, when the effect of the other independent variables are removed (i.e. adjusting / controlling for the other variables in the model). It indicates the nature of the relationship between the dependent variable (e.g. pre-operative VF-14 score) and the independent variable under consideration. The t-statistic and its observed significance level is used to test the null hypothesis that the population partial regression coefficient observed for a variable is zero. It indicates whether a significant relationship exists or not.

The accompanying analysis of variance tests several equivalent hypotheses :

- there is no linear relationship in the population between the dependent variable and the independent variables
- that all the population regression coefficients are zero
- that the population value for multiple R = 0.

  This is the correlation coefficient between the observed value of the dependent variable and the predicted value based on the regression model.

The validity of the regression models was tested through:

a. plotting a histogram of the standardised residuals. These should be normally distributed.

b. normal P-P plot of residuals of SIP and VR-SIP scores - this is a plot of the distribution of observed standardised residuals against a standard normal distribution. The observed residuals should lie close to the expected normal line.

Complete details of all models and accompanying diagnostic plots are presented in the Appendix C (C2, C3 and C4).

The presence of any important interactions in the model were examined using a multifactor general ANOVA.

7.3.5. Change in Score Post-Operatively

Paired t-tests and equivalent non-parametric tests (Wilcoxon Matched-Pair Signed Ranks Test and the Sign Test) were performed to assess the magnitude and statistical significance of the change in VF-14 scores, SIP and VR-SIP scores post-operatively, (at 4 and 12 months).

7.3.6 Responsiveness to Change

The minimum amount of change in VF-14 score, SIP score or VR-SIP score, that may be considered clinically significant in cataract patients is not known. Responsiveness to change, is the ability of an instrument to detect small but important change after surgery.[157][158] In addition to validity and reliability, responsiveness to change is recognised as an important characteristic of patient perceived measures which indicates the suitability of an instrument for measuring change. [158][159][160]

Responsiveness to change was considered in terms of effect size. Effect size has been suggested as a measure to assess responsiveness to change that provides a standard unit of measurement for comparison purposes.[160] Effect size is given by the ratio of the mean change in scores post-operatively and the standard deviation of the pre-operative scores. Its computation takes into account the variability in baseline scores as well as the change in scores after an intervention (pre- and post-operative in this case).[160] To allow for the presence of highly skewed score distributions, effect size was also computed and is presented as the ratio of the median change in score post-operatively and the inter-quartile range of pre-operative scores.[160]. Effect sizes for SIP and VR-SIP were computed for overall scores, dimension and category scores.

An effect size of 1.0 is equivalent to a change of one standard deviation in the sample. As a benchmark for assessing the relative magnitude of a change, it has been suggested that an effect size of 0.2 is a small, 0.5 is a moderate and 0.8 is a large effect size.[125]

7.3.7 Determinants of Change in Score Post-Operatively

The multifactor general ANOVA model was used to identify some of the determinants of change in scores. This method allowed for analysis of paired data (change in visual function score) and factored variables (e.g. presence of ocular comorbidity), whilst examining covariates that may be "determinants" of change in visual function post-operatively. It also provides information regarding the contribution made by covariates and factors to the model and their relationships with each other. The validity of the ANOVA analysis models were tested through :

a. tests for homogeneity of variance (Cochran's and Bartlett-Box tests) - these should give p-values well in excess of 0.05.

b. plotting the standardised residuals by cases - there should be no obvious pattern in the scatterplot.

c. Normal Q-Q plot of residuals of change in VF-14 score at 4 months or 12 months - this is a plot of observed residuals by residuals that would be expected if they had a normal distribution. The observed residuals should lie close to the expected normal line.

Details of all the models are provided in the Appendix D.

Models were first fitted to establish the relationship between change in visual function post-operatively and visual acuity i.e. pre-operative visual acuity in the better eye, and the change in better eye visual acuity post-operatively.

As patients had different levels of visual function or quality of life pre-operatively, their capacity for change after surgery was taken into account when identifying determinants of change after surgery. This required inclusion of the pre-operative score in the models. Although the pre-operative score is correlated with, and involved in the calculation of, the change in score post-operatively, its inclusion in the ANOVA models as a covariate was to control for its potential confounding effect on the relationship between change in score and visual acuity. Similarly when examining the relationship between change in score and change in better eye visual acuity post-operatively, the pre-operative better eye acuity was also included as a covariate to adjust for the capacity for change in visual acuity that was possible after surgery.

The presence of confounding was assessed by comparing the unadjusted and adjusted estimates for the regression coefficients for pre-operative better eye visual acuity and change in better eye visual acuity. Confounding was considered to be present if the estimate for the regression coefficients meaningfully changed when the variables for capacity for change were included in the model. The interpretation of a "meaningful" change was based on [161]:

- the comparison of the size of the estimates numerically

- the examination of the effect on the confidence intervals of the adjusted and unadjusted regression coefficients - whether adjusting for the confounding variable had any effect on the precision of the estimate for the regression coefficient - i.e. were the confidence intervals for the adjusted regression coefficients narrower than those for the unadjusted estimates.

8. SUMMARY OF METHODS

The methods used to achieve the objectives of this study may be summarised as follows :

- The study method was that of a prospective study design of patients admitted for surgery for age related cataract in their first eye, some of whom went on to have surgery to their second eye during the study period. Patients were followed up at 4 months and 12 months after surgery.

- The main measures of outcome were both clinical (visual acuity) and patient perceived (visual functioning and quality of life)

- The instruments used for these main outcome measures were -

  Snellen visual acuity - the surgery eye, the better eye, and v-person acuity

  Visual functioning - the VF-1

  Quality of life - the Sickness Impact Profile (SIP)

  Quality of life affected by vision - the VR-SIP (modified SIP)

- The main statistical methods using multiple regression and analysis of covariance methods, provided measures of association describing and examining the relationships between visual acuity, visual function and quality of life.

Chapter 5.

THE CATARACT OUTCOME STUDY : RESULTS

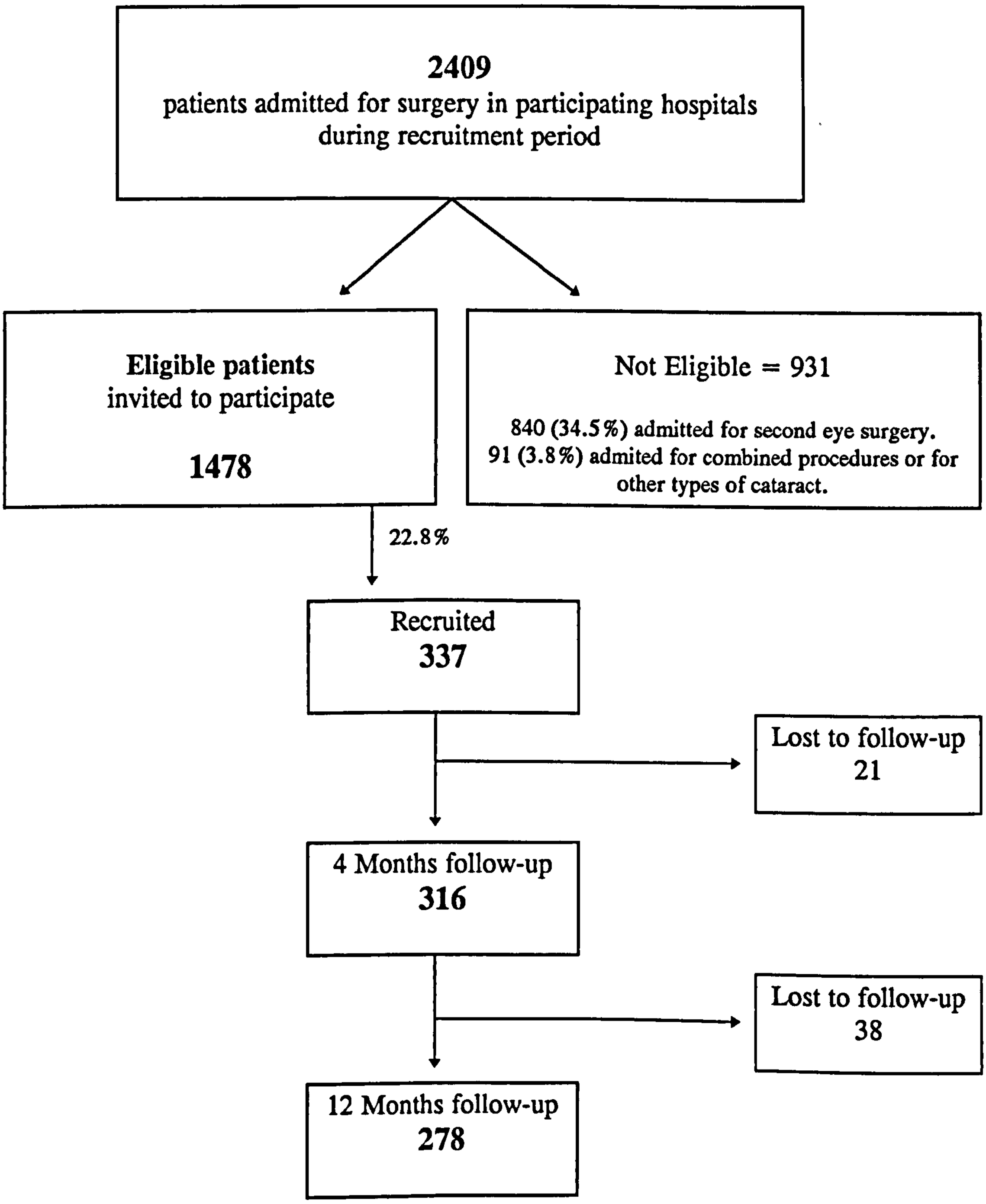
SAMPLE CHARACTERISTICS, DATA COMPLETENESS, CLINICAL OUTCOMES AND MEASURES OF VISUAL ACUITY

1. RECRUITMENT

There were 2409 patients that were admitted for cataract surgery in the participating hospitals, during the recruitment period (May 1993 to August 1994). Of these, 840 (34.5%) patients were being admitted for second eye surgery and 91 (3.8%) patients were admitted for combined procedures or for surgery for other types of cataract, and were not eligible for inclusion. There were thus 1478 eligible patients that were invited to participate in the study of whom 337 (22.8%) consented and were recruited to the study. (Figure 5.1)

A random sample of 376 patients who were eligible for inclusion but that did not take part in the study was obtained. This represented a third (33%, n=376/1141) of all non-participants. Participants were compared with the non-participants and with the patients included in the National Cataract Surgery Study. As presented in Table 5.1, they were found to be similar and no significant differences were observed in terms of age and sex.

Figure 5.1 Recruitment of patients to the study, and follow-up.



Total lost to follow-up = 59/337 = 17.5%

Table 5.1 Comparison of the Study Sample with Non-Participating Patients and a National Sample of Cataract Patients

	Participants	Non-Participants *	National Sample #
	n=337	n=376	n=1495
	n (%)	n (%)	n (%)
Age (yrs)			
50-64	35 (11.3)	36 (9.6)	199 (13.3)
65-74	99 (29.4)	108 (28.7)	449 (30)
>=75	200 (59.3)	232 (61.7)	850 (56.7)
		** Chi-square=0.69 df=2; p=0.71	## Chi-square=1.22 df=2; p=0.54
Sex			
males	131 (38.9)	121 (32.1)	576 (38.5)
females	206 (61.1)	253 (67.9)	919 (61.5)
		** Chi-square=3.29 df=1; p=0.07	## Chi-square=0.014 df=1; p=0.91

* Eligible patients that did not participate in this study
** Comparison between participants (study sample) and non-participants

\# Sample from the National Cataract Surgery Survey
Comparison between participants (study sample) and the national sample of patients

1.1 SIP Responders and Non-Responders

Of the 337 participants, 273 (81%) patients had complete interviews , providing responses to the SIP and VR-SIP before surgery. These patients were compared with those that did not complete the interview. No significant differences were demonstrated between the groups in terms of marital status, living alone or not, and pre-operative visual acuity in the surgery eye. This was also true for length of stay. (Table 5.2)

Table 5.2 SIP and VR-SIP : Responders and Non-Responders before surgery.

	SIP Respondents n=273 n (%)	SIP Non-Respondents n=64 n (%)
Marital Status		
married	137 (50.2)	35 (54)
not married	136 (49.8)	29 (46)
	Chi-square=0.42; df=1; p=0.52	
Living alone	115 (42.2)	28 (44.1)
Not living alone	158 (57.8)	36 (55.9)
	Chi-square=0.06; df=1; p=0.81	
Visual Acuity in Surgery Eye (n=250)		
6/6 to 6/12	59 (23.6)	10 (18.8)
6/18 to /624	112 (44.8)	27 (51)
6/36 to 6/60	42 (16.8)	10 (18.8)
less than 6/60	37 (14.8)	6 (11.4)
	Chi-square=1.27; df=3; p=0.74	
Length of Stay (n=254)		
In-patient	135 (53.1)	36 (65.5)
Day-case	119 (46.9)	19 (34.5)
	Chi-square=2.77; df=1; p=0.09	

2. LOSSES TO FOLLOW-UP

At 4 months after surgery 21 patients were lost to follow-up. At 12 months after surgery there were an additional 38 patients lost to follow-up, making a total of 59 patients by that time, (17.5% of the recruited sample). (Figure 5.1)

Reasons for losses to follow-up were identified for 24 patients, and these were :

Deceased	-	5 patients (range 64 to 92 yrs, mean 79.6 yrs)
Ill-health	-	5 patients
Moved away	-	5 patients
Uncooperative patient	-	2 patients
Dissatisfied with surgery	-	1 patient
Did not want to continue	-	6 patients

No reason was ascertained for the remaining 35 patients lost to follow-up during the study. This was after at least two attempts by the interviewers (letter and phone-calls), and two attempts from the hospital (letter and phone call).

When the patients lost to follow-up during the study were compared with those with continued follow-up, no major differences were apparent in terms of age, sex and ocular comorbidity in the surgery eye. Patients lost to follow-up appeared to have poorer better eye visual acuity on admission, but these differences were not found to be statistically significant. (Table 5.3)

Table 5.3 Characteristics of patients followed up after surgery and those lost to follow-up.

	Patients Followed to 12 months n=278 n (%)	Patients lost to Follow-Up by 12 months n=59 n (%)
Age on admission (yrs)		
50-64	28 (10)	10 (17)
65-74	86 (31)	13 (22)
>=75	164 (59)	36 (61)
	Chi-square=3.39, df=2, p=0.18	
Sex		
males	112 (40)	19 (32)
females	166 (60)	40 (68)
	Chi-square=1.34, df=1, p=0.25	
Visual Acuity on admission in Better Eye		
6/6 to 6/12	161 (61.7)	21 (48.8)
6/18 to /624	78 (29.9)	16 (37.2)
636 to 6/60	16 (6.1)	5 (11.6)
less than 6/60	6 (2.3)	1 (2.3)
total	261	43
	Chi-square=3.27, df=3, p=0.35	
Ocular Comorbidity on Admission in Surgery Eye		
present	184 (69)	27 (61)
absent	81 (31)	17 (39)
total	265	44
	Chi-square=1.13, df=1, p=0.29	

2.1 Losses to Follow-Up - SIP Responders

60 of the 273 patients who had completed SIP and VR-SIP before surgery, failed to do so 4 and 12 months after surgery. However, no significant differences were demonstrated between patients followed -up and those lost to follow-up in terms of pre-operative characteristics, as presented in Table 5.4.

Table 5.4 Characteristics of patients with complete SIP and VR-SIP, followed up after surgery and those lost to follow-up

	Patients Followed Up to 12 months n=213 n (%)	Patients lost to Follow-Up by 12 months n=60 n (%)
Age on admission (yrs)		
50-64	30 (9)	10 (17)
65-74	63 (30)	20 (33)
>=75	130 (61)	30 (50)
	Chi-square=3.45, df=2, p=0.18	
Sex		
males	83 (39)	26 (43)
females	130 (61)	34 (57)
	Chi-square=0.37, df=1, p=0.54	
Marital Status		
married	101 (47.4)	36 (60)
not married	112 (52.6)	24 (40)
	Chi-square=2.95, df=1, p=0.09	
Living alone	123 (58)	42 (70)
Not Living alone	90 (42)	18 (30)
	Chi-square=2.93, df=1, p=0.09	

3. DATA QUALITY

3.1 Patient Interview

Data collection from the patient interview was complete for all the main measures of interest.

Table 5.5 Data Quality - Completeness of Recording : Patient Interview

Field	Total Number of Records	Number of Records with Missing Data	% records with Missing Data
On Admission (n=337) :			
Age	337	0	0.0
Sex	337	0	0.0
Global assessment of vision (A1)	337	0	0.0
Global assessment of vision (A2)	337	0	0.0
Cataract Symptom Score	337	0	0.0
VF-14	337	0	0.0
Comorbidity "bothersome" score	337	0	0.0
SIP *	273	0	0.0
VR-SIP *	273	0	0.0
At 4 Months After Surgery (n=316) :			
VF-14	316	0	0.0
SIP *	213	0	0.0
VR-SIP *	213	0	0.0
At 12 Months After Surgery (n=278) :			
VF-14	278	0	0.0
SIP *	217	0	0.0
VR-SIP *	217	0	0.0

3.2 Clinical Data

Before surgery, clinical data were available for 316 (94%, n=316/337) recruited patients. At 4 months after surgery, clinical data were available for 279 (82.8%, n=279/337) patients with interview data. At 12 months 243 (72.1%, n=243/337) patients had clinical data to accompany interview data.

The proportion of clinical data forms with missing data ranged from 0.8% to 9.7% by item. Most items had complete data for over 95% of patients with the exception being complications within 48 hours of surgery.

Table 5.6 Data Quality - Completeness of Recording : Clinical Data

Field	Total Number of Records	Number of Records with Missing Data	% records with Missing Data
On Admission (n=316) :			
Visual Acuity - Surgery Eye	316	6	1.9
Visual Acuity - Fellow Eye	316	9	2.9
Ocular Comorbidity	316	0	0.0
Medical Comorbidity	316	0	0.0
Comorbidity "bothersome" score	316	0	0.0
Peri-Operatively (n=309) :			
Intra-operative complications	309	0	0.0
Complications within 48 hours	309	30	9.7
At 4 Months After Surgery (n=279) :			
Visual Acuity - Surgery Eye	279	9	3.2
Visual Acuity - Fellow Eye	279	12	4.3
Complications	279	0	0.0
At 12 Months After Surgery (n=243) :			
Visual Acuity - Surgery Eye	243	2	0.8
Visual Acuity - Fellow Eye	243	6	2.5
Complications	243	2	0.8

4. CLINICAL OUTCOMES

Clinical outcomes are presented in terms of visual acuity in the surgery eye at 4 months after surgery, and the occurrence of complications.

4.1 Visual Acuity

265 patients had complete data on visual acuity in the surgery eye both before and 4 months after surgery. Following surgery, visual acuity in the surgery eye underwent a significant shift. 84.5% (224/265) of patients achieved a good visual acuity of 6/12 or better in the surgery eye by 4 months. (Chi-square = 198.9, df = 3, p-value <0.001).

Table 5.7 Visual acuity in surgery eye on admission and 4 months after surgery

		Visual Acuity at 4 months after surgery			
Visual Acuity on Admission	**Number of Patients (%)**	**6/6 to 6/12 n (row %)**	**6/18 to 6/24 n (row %)**	**6/60 to 6/36 n (row %)**	**less than 6/60 n (row %)**
6/6 to 6/12	63 (23.8)	59 (93.7)	3 (4.8)	0 (0)	1 (1.6)
6/18 to 6/24	122 (46)	104 (85.2)	17 (13.9)	1 (0.8)	0 (0)
6/36 to 6/60	46 (17.4)	38 (82.6)	6 (13)	2 (4.3)	0 (0)
less than 6/60	34 (12.8)	23 (67.6)	5 (14.7)	3 (8.8)	3 (8.8)
All	265 (100)	224 (84.5)	31 (11.7)	6 (2.3)	4 (1.5)

This was comparable to the findings in the National Cataract Surgery Study, in which 80% of patients achieved a good visual acuity after surgery. The observed difference between these two samples in the proportion of patients achieving good visual acuity

was 4.5%, (S.E. of difference = 2.57; 95% C.I. for this difference was -2.8 to 9.8) and was not statistically significant.

4.2 Complications of Surgery

The frequency of major complications during each post-operative period was similar to the sample in the National Cataract Surgery Study. With the exception of capsule rupture without vitreous loss which occurred less frequently in this sample, no significant differences were observed between the samples for the other major complications.

Table 5.8 Occurrence of major complications

Type of Complication	Study Sample n=241 Number with Complication (%)	National Sample * n=998 Number with Complication (%)	Observed Difference between Proportions	S.E. of the Observed Difference	95% C.I. for the Observed Difference
Peri-operative period :					
Capsule rupture					
without vitreous loss	2 (0.8)	39 (3.9)	- 3.1	0.8	- 4.7 to -1.4
with vitreous loss	4 (1.6)	11 (1.1)	0.6	0.9	- 1.2 to 2.4
Within 1 month :					
Endophthalmitis	2 (0.8)	3 (0.3)	0.5	0.7	- 0.7 to 1.8
At 4 months :					
Retinal detachment	0 (0)	1 (0.1)	- 0.1	0.1	- 0.3 to 0.1
Cystoid macular oedema	2 (0.8)	12 (1.2)	- 0.4	0.7	- 1.7 to 1.0
Post. capsule opacification	13 (5.5)	63 (6.3)	- 0.8	1.7	- 4.1 to 2.4

* - Sample from the National Cataract Surgery Study

5. MEASURES OF VISUAL ACUITY

There were 312 patients with visual acuity data in both eyes on admission. 267 (86%) patients had complete visual acuity data in both eyes at 4 months and 239 (77%) patients at 12 months. Visual acuity was considered in terms of the best corrected Snellen visual acuity for the surgery eye, and the better eye, and also in terms of the VP% score (person visual acuity score). The distributions of surgery eye visual acuity, better eye visual acuity and VP% score, pre-operatively and post-operatively, were all skewed.

On admission, 22.5% of patients had a visual acuity between 6/6 and 6/12 in the surgery eye; with 60% of patients having this level of acuity in the better eye at that time. After surgery, 85% of patients had achieved a good visual acuity outcome of 6/6 to 6/12 at 4 months in the surgery eye, with 90% of patients having this level of visual acuity in the *better* eye. Pre-operatively, 38% (117/312) of surgery eyes were the better eye. Post-operatively, 85% (226/267) of surgery eyes were the better eye at 4 months; and 82% (195/239) of surgery eyes were the better eye at 12 months.

5.1 Correlations between measures of visual acuity

As the distributions of all measures of visual acuity were skewed, the Spearman correlation coefficients are presented in Table 5.9. (Pearson correlation coefficients were also computed and these were of a similar order of magnitude).

Before surgery, better eye acuity and VP% score were highly correlated (0.91) and the surgery eye correlated better with VP% score (0.58) than with better eye visual acuity (0.39). After surgery, as the surgery eye became the better eye in most cases, the surgery eye acuity and better eye acuity were highly correlated (0.89 at 4 months and 0.82 at 12 months). VP% score correlated highly with both, but slightly better with better eye visual acuity, at both 4 and 12 months.

Table 5.9. Correlation matrix : measures of visual acuity

		VSEYADM	VBEYADM	VPADM	VSEY4M	VBEY4M	VP4M	VSEY12M	VBEY12M
Surgery Eye Visual Acuity Pre-Op	: VSEYADM	--	--	--	--	--	--	--	--
Better Eye Visual Acuity Pre-Op	: VBEYADM	0.39	--	--	--	--	--	--	--
VP% Score Pre-Op	: VPADM	-0.58	-0.91	--	--	--	--	--	--
Surgery Eye Visual Acuity 4 Months	: VSEY4M	0.14	0.2	-0.23	--	--	--	--	--
Better Eye Visual Acuity 4 Months	: VBEY4M	0.15	0.34	-0.35	0.89	--	--	--	--
VP% Score 4 Months	: VP4M	- 0.23	-0.55	0.58	-0.67	-0.73	--	--	--
Surgery Eye Visual Acuity 12 Months	: VSEY12M	0.13 *	0.26	0.27	0.59	0.58	-0.51	--	--
Better Eye Visual Acuity 12 Months	: VBEY12M	0.12 *	0.34	-0.33	0.58	0.61	-0.54	0.82	--
VP% Score 12 Months	: VP12M	-0.11 *	-0.36	0.41	-0.45	-0.49	0.56	-0.63	-0.66

All are Spearman Correlation Coefficients, p-value <0.01, except where indicated by * for p-values >0.05

6. DISCUSSION

6.1 Study Method

6.1.1 Possible sources of bias :

The biases of particular concern in this study were *selection bias* and those that may have been introduced from *losses to follow-up*.

The sample of patients recruited into the study represented about a quarter of all patients eligible for inclusion. Since all the eligible patients were identified and invited to participate, it was unlikely that a selection bias would have been introduced at that stage of the study. However, the subsequent selection factors that may have been operating would have been characterised by a possible "volunteer" effect. There was no evidence for this, at least in terms of age and sex on admission for surgery, as the sample obtained was comparable to a random sample of those non-participating patients that were having surgery in the hospitals during the same time period; and was also comparable to a larger sample of patients from the National Cataract Surgery Study in this respect. It was possible however, that the study participants may have differed from non-participants in other, unrecorded respects.

64 (19%) patients did not complete the interview, and so no information on health or vision-related quality of life was obtained from them. No significant selection factors in terms of age, sex, marital status, living alone or not, and visual acuity on admission were observed when this group was compared to the patients that had completed the interview.

59 (17.5%) of patients were lost to follow-up. Despite having locally based interviewers who established good contacts with the patients, a reason for loss to follow-up was still not ascertained for half of these patients. However, no significant differences were observed between the patients lost to follow-up and the patients that were followed-up throughout the course of the study, in terms of pre-operative characteristics. Similarly, no significant differences were observed amongst the

patients with complete interview (SIP and VR-SIP) and those amongst them that were lost to follow-up.

In summary, it was considered that a representative sample of cataract patients was obtained and losses to follow-up were unlikely to have introduced any major biases into the post-operative findings.

6.1.2 Data Quality

Considerable effort had been made to standardise methods and to ensure prospective data collection, without interfering with routine clinical practice. It was still possible that some data were obtained retrospectively from the hospital clinical notes after the admission episode or the follow-up assessment at 4 months, and that their quality or completeness could have introduced an *observation bias*. However, as the 12 month clinical assessment was made in a dedicated specially arranged clinic. it is unlikely that this occurred at that time.

Overall, clinical data were complete for over 95% of cases for most items, including visual acuity recording in the fellow eye. The validity and reliability of clinical data collection was probably high as the forms were completed by ophthalmologists. As the events of interest were confined to those that were clinically significant, this overcame problems with interpretations of definitions and it was unlikely that important misclassifications occurred.

The patient interview was standardised and contained specific, closed questions, and the interviewers were trained to standardise its administration. One interviewer conducted all the interviews in his/her area, and consequently each patient had interviews conducted by the same interviewer. Although this removed any inter-interviewer variability in eliciting responses from the patients, it was still possible for a systematic bias to be operating for the individual interviewer during interview conduction. However, as the interview did not require open responses, and it contained instructions for administration within the construct of the major questions, it

was unlikely that any significant errors of this type were introduced from the patient interview

6.2. Clinical Outcomes

The clinical outcomes were found to be typical for visual acuity after surgery and for the occurrence of complications, when compared to the national sample from the National Cataract Surgery. On this basis, subsequent analysis of patient perceived measures and their relationships with visual acuity was then conducted.

6.3 Measures of Visual Acuity

The surgery eye visual acuity provided a direct assessment of cataract and cataract surgery, on the resultant visual impairment (before and after surgery) in the affected eye. Although the surgery eye visual acuity was highly correlated with better eye visual acuity after surgery, it did not represent all the better eyes. At least 15% of surgery eyes were not the better eyes four months after surgery and 18% of surgery eyes at one year were not the better eyes. The VP% score and better eye acuity were highly correlated before and after surgery. As the calculation of the VP% score was weighted in favour of the better eye acuity this was not surprising.

7. SUMMARY OF FINDINGS

The main findings reported in this chapter may be summarised as follows :

- a representative sample of cataract patients was obtained

- losses to follow-up were unlikely to have introduced bias into the post-operative findings

- interview data were complete for all items

- clinical data were complete for 95% of the main items

- the clinical outcomes were typical

- the surgery eye provided a direct assessment of cataract and surgery on the resultant visual impairment in the affected eye

- VP% score and better eye visual acuity were highly correlated before and after surgery

Chapter 6.

THE CATARACT OUTCOME STUDY : RESULTS

VISUAL FUNCTIONING - THE VF-14

1. INTRODUCTION

This chapter will present the findings related to visual functioning (functioning in vision-dependent activities performed in everyday life) associated with cataract and the impact surgery may have on it.

The reliability and validity of the VF-14, the index of visual functioning used in this study, are considered first. Pre-operative and post-operative findings are then presented in separate sections, but follow the same format :

- a description of visual functioning at that time (before surgery or 4 and 12 months after surgery)
- a description of the change in visual function after surgery
- the responsiveness of the VF-14 to change after surgery

2. RELIABILITY AND VALIDITY OF THE VF-14

2.1 Reliability of the VF-14

The reliability of the VF-14 as assessed in terms of its internal consistency was given by Cronbach's alpha. The findings are presented in Table 6.1.

The overall Cronbach's alpha was 0.74 indicating that the index is reliable. The standardised item alpha was 0.75, which is the value if all of the items were standardised to have a variance of 1. Since the items on the VF-14 had fairly comparable variances, little difference between these two alphas was observed. If the question "Drivers 1" (difficulty driving during the day) was omitted, then an alpha of 0.7646 was achieved.. As this was a modest change in the overall alpha it was felt that deletion of this item from the index was unlikely to have any significant effect on improving the homogeneity of the index. Elimination of the remaining items had little change on alpha (Table 6.1).

The item-total correlation is also presented in Table 6.1. It is the correlation of each individual item with the overall scale score omitting that item. The item-total correlations range from 0.06 to 0.67. It has been suggested that items should correlate with the total score above 0.20, and items with lower scores should be discarded [165][166]. The item with the lowest item-total correlation related to difficulty driving during the day. This item was not discarded on the basis that any effect that this may have had on internal consistency would have been modest. More importantly the instrument was designed to cover a spectrum of vision-dependent activities performed in everyday life that may be affected by cataract, and by omitting this item, content validity may have been compromised. The aim of this instrument is to draw valid inferences on visual functioning amongst cataract patients, and in this context it will depend more on content validity than internal consistency, as it is concerned with vision dependent activities that are quite heterogeneous (near, intermediate and distance vision).

Table 6.1 **Reliability of the VF-14 Index : Internal Consistency. Item-Total Statistics. N of cases = 337. N of items = 14.**

Item *	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Alpha if Item Deleted
A40	64.92	418.62	0.62	0.59	0.70
A41	62.87	405.03	0.67	0.65	0.69
A42	59.98	435.58	0.49	0.39	0.71
A43	60.40	445.67	0.41	0.31	0.72
A44	61.27	449.94	0.38	0.27	0.72
A45	61.73	429.88	0.48	0.32	0.71
A46	64.84	445.15	0.34	0.20	0.73
A47	61.49	415.59	0.55	0.38	0.70
A48	65.31	474.56	0.12	0.05	0.75
A49	67.41	495.17	0.11	0.09	0.74
A50	61.03	472.71	0.14	0.19	0.75
A51	61.35	438.01	0.49	0.32	0.71
Drivers 1	65.93	479.93	0.06	0.35	0.76
Drivers 2	67.16	482.94	0.22	0.34	0.74

Scale Statistics :
Scale Mean = 68.13
S.D. = 22.6
Variance = 510.69

Reliability Coefficients on 14 items :
Cronbach's Alpha = 0.74
Standardised Item Alpha =0.75

* A40 to A51 - items relating to vision-dependent activities in VF-14 (Appendix B3).
Drivers 1 and Drivers 2 - items in VF-14 relating to current drivers and difficulty driving (Appendix B3).

2.2 Validity of the VF-14

2.2.1 Content Validity

As indicated above, the final instrument containing 14 items was produced following a review by an expert national advisory panel composed of ophthalmologists and optometrists to ensure that : the list contained the full spectrum of functional

limitations experienced by cataract patients; to exclude or combine any items that may constitute functionally equivalent task with respect to vision; and to specify relevant functional activities that had not yet been identified.[136] In doing so, this exclusively professional and clinical expert panel, assessed the content validity of the instrument, and found this to be satisfactory.

2.2.2 Criterion Validity

The correlations between pre-operative VF-14 scores and pre-operative visual acuity, global self rating of function for the overall amount of trouble or satisfaction patients had with their vision are presented in Table 6.2.

Both Pearson and Spearman correlation coefficients were computed (Appendix D1). Since the pre-operative VF-14 score was not normally distributed, the Spearman correlation coefficients were used to examine these associations.

The VF-14 scores correlated moderately with the global assessments of vision for "trouble" and "dissatisfaction" with vision (-0.5553 and -0.4880 respectively) and were better than the correlations with better eye visual acuity (-0.4763) and VP% score (0.4537). The correlation between VF-14 score and visual acuity in the better eye and VP% score were higher than for the visual acuity in the surgery eye (0.2065). It would seem that visual function in terms of ability to perform vision-dependent activities, is determined more by the visual acuity in the better eye than the surgery eye (the affected eye and which is most likely to be the worst eye in the majority of cases).

Table 6.2 Criterion Validity of the VF-14 Index
Correlation Matrix with other measures of vision and function : SPEARMAN Correlation Coefficients

	VFSD	BV	V-Person	SV	"Trouble"	"Satisfaction"	SIP	VR-SIP
VF score on admission (VFSD)	---							
Vision in Better Eye on admission (BV)	0.4763	---						
V-Person Score vision for person on admission	0.4537	-0.9095	---					
Vision in Surgery Eye on admission (SV)	-0.2065	0.3949	-0.5773	---				
Amount of "trouble" with vision	-0.5553	0.3773	-0.3724	0.1919 *	---			
Amount of "dissatisfaction" with vision	-0.488	0.3252	-0.3232	0.1884 *	0.5445	---		
SIP Score on Admission (SIP)	-0.3713	0.3359	-0.3349	0.1818 *	0.2200	0.2155	---	
Vision-Related SIP Score (VR-SIP) on admission	-0.7054	0.3391	-0.3436	0.1696 *	0.4833	0.3978	0.4037	---

* Spearman Correlation Coefficients with a p-value <=0.007
All other Spearman Correlation Coefficients presented have a p-value <0.0001

3. PRE-OPERATIVE VISUAL FUNCTIONING

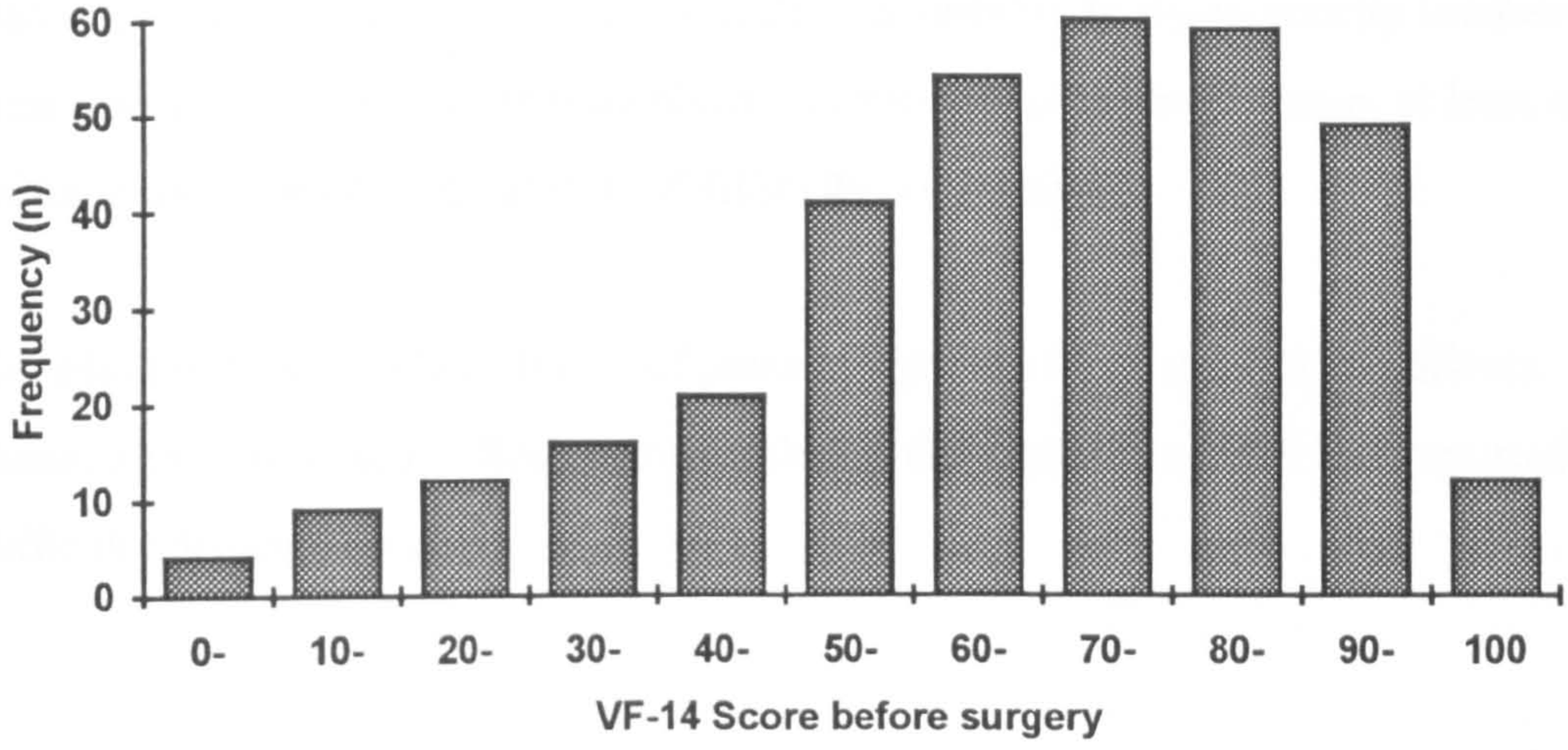
The mean VF-14 score on admission for cataract surgery was 68.1 (s.d. 22.6), the median was 72.2, with the scores ranging from 0 to 100. The distribution of scores was skewed towards the higher scores (less disability) - Figure 6.1 and Table 6.3. Twelve patients (3.6%) had a maximum score of 100, pre-operatively. Whilst it would not be possible for these patients to show any gain in visual function after surgery, they could show loss. 35.6% of all patients had a score of 80 or more before surgery. 18.4% patients had a score of less than 50.

Table 6.3 Distribution of Pre-operative VF-14 Scores (on Admission for Cataract Surgery).

VF-14 Score	n	%
0 -	4	1.2
10 -	9	2.7
20 -	12	3.6
30 -	16	4.7
40 -	21	6.2
50 -	41	12.2
60 -	54	16.0
70 -	60	17.8
80 -	59	17.5
90 -	49	14.5
100	12	3.6
ALL	337	100.0

Mean score = 68.13
S.D. = 22.59
S.E. = 1.23

Figure 6.1 Distribution of Pre-operative VF-14 Scores. n = 337



No statistical transformation was effective in normalising the distribution of pre-operative VF-14 scores, so the untransformed VF-14 score was used in all further analysis.

The mean number of items that contributed to the score was 10.5 (s.d. 1.5). 80% of patients had 10 or more items contributing to the score .

3.1 Characteristics of Response to VF-14 Items

The responses to the individual items is presented in Table 6.4. At least half of all patients reported "a great deal of difficulty" or inability to do an activity involving near vision. For activities that involved intermediate or distance vision, at least a third of patients reported "a great deal of difficulty" or inability.

On admission only 28% (94/337) of patients reported they were current drivers. Of these, a third reported difficulty driving during the day-time and 82.3% reported difficulty driving at night.

Table 6.4 Visual Function (VF-14) : Item Responses Before Surgery. N=337

VF-14 Item	Number (%) Patients Reporting Difficulty with Item		Number (%) Patients Reporting "a great deal difficulty "or unable to do" item	
Near Vision :				
Reading small print	290	(86.1)	227	(67.4)
Reading book / newspaper	233	(69.1)	142	(42.1)
Fine handwork : sewing / carpentry	177	(52.5)	122	(36.2)
Writing letters / cheques / filling forms	132	(39.2)	71	(21.1)
Intermediate Vision :				
Watching TV	184	(54.6)	47	(14.0)
Seeing steps / kerbs	164	(48.7)	53	(15.8)
Recognising people close by	100	(29.7)	49	(14.5)
Reading large print	71	(21.1)	31	(9.2)
Playing games : bingo / card etc.	62	(18.4)	30	(8.9)
Cooking	61	(18.1)	18	(5.4)
Distance Vision :				
Reading signs : street / shop / traffic	163	(48.4)	66	(19.6)
Sports : bowling / golf / tennis	30	(8.9)	18	(5.3)
Current Drivers (n=94)				
Difficulty driving during day-time	31	(33.0)		
Difficulty driving at night	78	(82.3)		

4. POST-OPERATIVE VISUAL FUNCTIONING AFTER SURGERY

There were 316 (93.8%) patients with complete data 4 months after surgery. Their mean VF-14 score was 88.5 (s.d.=17.16; 95% C.I. 86.6 to 90.4); the median was 95.4 (inter-quartile range = 16.5), with the scores ranging from 7.5 to 100. This distribution was highly skewed towards the higher scores (less disability) and could not be effectively normalised by statistical transformation. (Table 6.5 and Figure 6.2). 81% of all patients achieved a score of 80 or more at this time, with 35% of all patients having a maximum score of 100.

At 12 months after surgery there were 278 (82.5%) patients with complete data. Their mean score was 91.2 (s.d. =14.4, 95% C.I. 89.4 to 92.9); median was 97.6 (inter-quartile range = 11.5), with scores ranging from 2.5 to 100. 85.7% of all patients had achieved a score of 80 or more at this time. 34% of all patients had a maximum score of 100. The distribution was highly skewed towards the higher scores. (Table 6.5 and Figure 6.3).

Table 6.5 Frequency Distribution of VF-14 Scores After Surgery.

	AT 4 MONTHS N= 316		AT 12 MONTHS N = 278	
VF-14 SCORE	n	%	n	%
0 -	1	0.3	1	0.4
10 -	1	0.3	1	0.4
20 -	6	1.9	0	0.0
30 -	3	0.9	2	0.7
40 -	5	1.6	2	0.7
50 -	6	1.9	6	2.2
60 -	9	2.8	9	3.2
70 -	29	9.2	19	6.8
80 -	49	15.5	33	11.9
90 -	97	30.7	90	32.4
100 -	110	34.8	115	41.4

Figure 6.2 Distribution of VF-14 Scores at 4 Months after Surgery.
n = 316

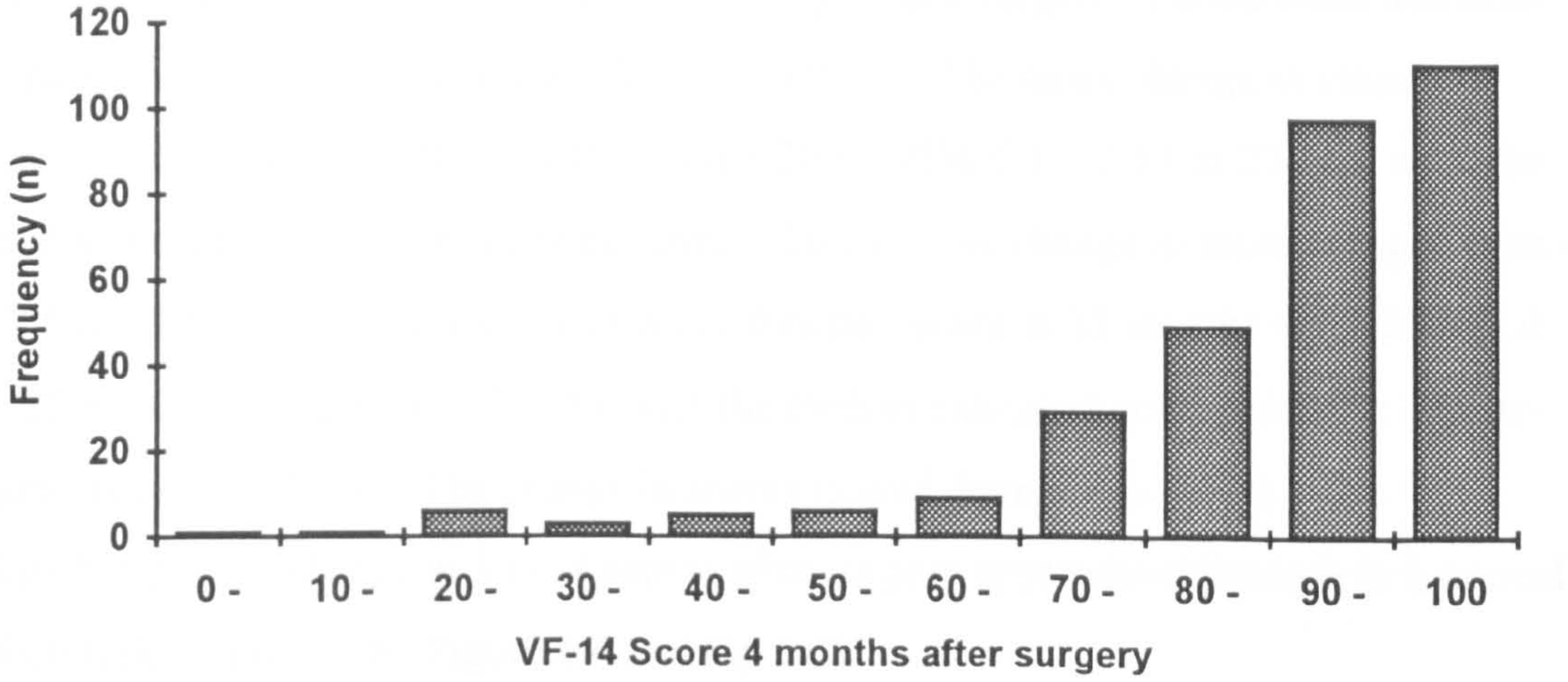
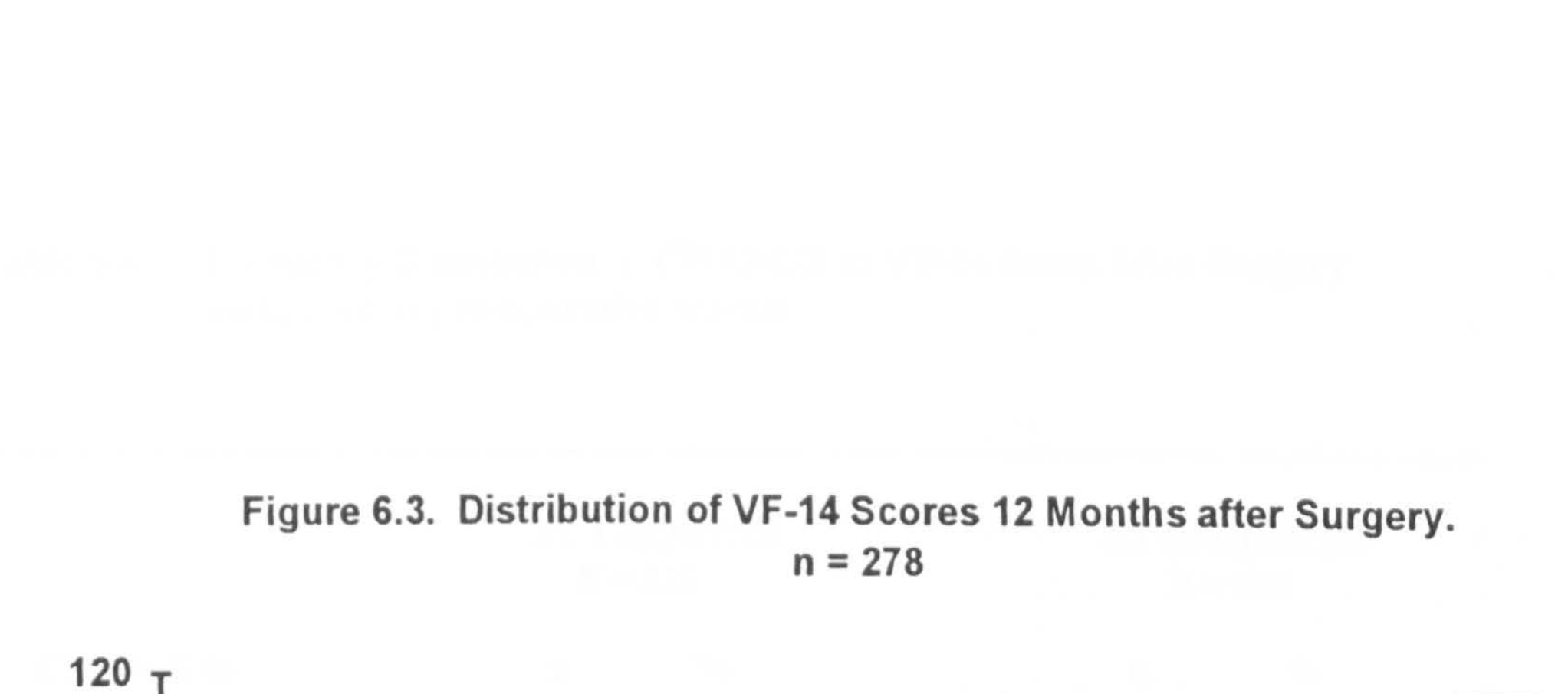


Figure 6.3. Distribution of VF-14 Scores 12 Months after Surgery.
n = 278



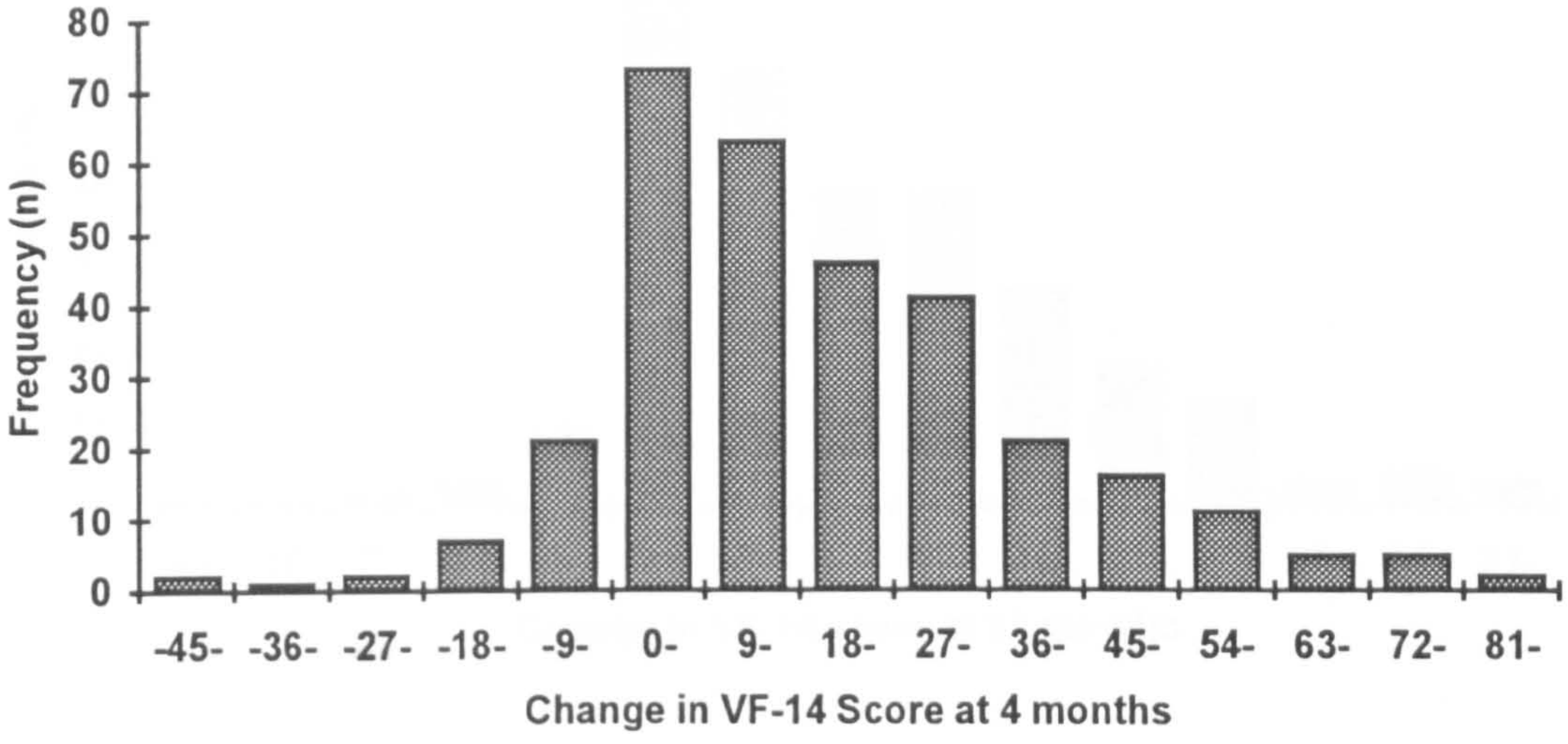
5. CHANGE IN VISUAL FUNCTIONING AFTER SURGERY

A significant improvement in visual function was observed at both 4 months and 12 months after surgery, compared to functioning before surgery. Paired t-test and non-parametric tests gave 2-tailed p-values of <0.0001. The mean change in visual function score at 4 months was 19.8 (s.d.= 20.9 ; 95% C.I. 17.53 to 22.16), with the median being = 15.9 (inter-quartile range = 26.2). The change in scores ranged from -37.5 to 87.5. The mean change in visual function score at 12 months was 22.69 (s.d. = 20.8; 95% C.I. 20.24 to 25.15), with the median change in score being 20.1 (inter-quartile range = 27.9). The change in scores ranged from -50 to 86.36. The distributions for change in VF-14 scores after surgery approximated better to a normal distribution (Table 6.6, Figure 6.4 and Fig 6.5)

Table 6.6 Frequency Distribution : CHANGE in VF-14 Score After Surgery (compared to pre-operative scores)

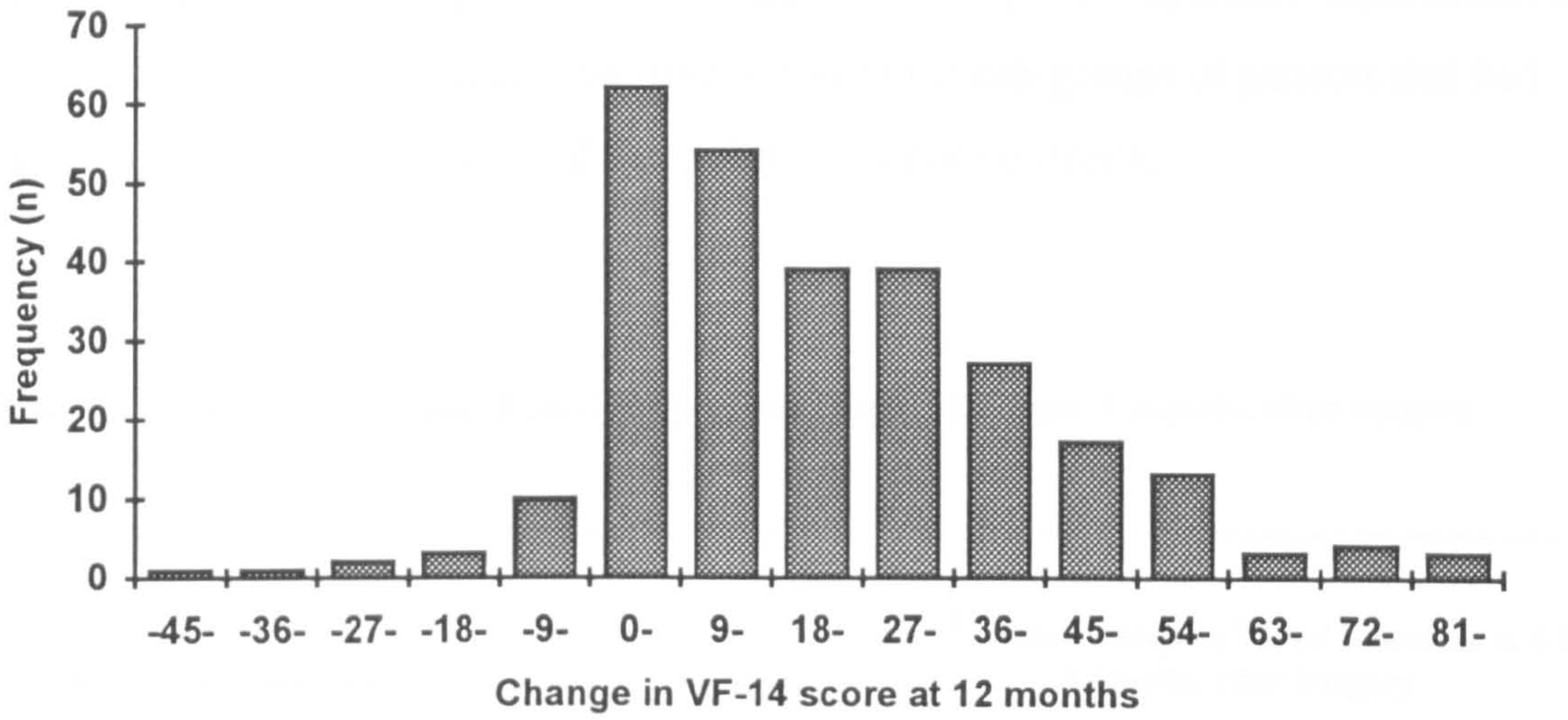
CHANGE in VF-14 Score	AT 4 MONTHS N = 316		AT 12 MONTHS N = 278	
	n	%	n	%
-45 -	2	0.6	1	0.4
-36 -	1	0.3	1	0.4
-27 -	2	0.6	2	0.7
-18 -	7	2.2	3	1.0
- 9 -	21	6.6	10	3.6
0 -	73	23.1	62	22.3
9 -	63	19.9	54	19.4
18 -	46	14.6	39	14.0
27 -	41	13.0	39	14.0
36 -	21	6.6	27	9.7
45 -	16	5.1	17	6.1
54 -	11	3.5	13	4.7
63 -	5	1.6	3	1.0
72 -	5	1.6	4	1.4
81 -	2	0.6	3	0.4

Figure 6.4. Distribution of CHANGE in VF-14 Score at 4 Months After Surgery. n = 316



Of the 316 patients, 267 (84.6%) had improved VF-14 scores, there was no change in 16 (5%) patients, and 33(10.4%) scored less after surgery. There was not much capacity for change (in the direction of gain) in the sixteen patients who did not change their VF-14 score post-operatively. Eleven of these patients had a maximum score of 100 pre-operatively, and the remaining 5 patients had scores ranging from 75 to 97.7. Ten patients had good visual acuity of 6/6 to 6/12 in the better eye before surgery and all of them had good post-operative acuity in the better eye. Of the thirty-three patients who lost visual function after surgery, 18 had pre-operative VF-14 scores of 80 or more and 23 patients had good visual acuity in the better eye both pre-operatively and after surgery. There were no differences in age, sex or the presence of ocular comorbidity amongst patients who either gained VF post-operatively, lost VF or did not change.

Figure 6.5. Distribution of CHANGE in VF-14 Scores 12 Months after Surgery. n = 278



Of the 278 patients, 248 (89.2%) had improved VF-14 scores, there was no change in VF-14 score in 13 (4.7%), and 17 patients (6.1%) had lost visual function after surgery. There was not much capacity for change in the thirteen patients who did not have any change in visual function at this time. Ten of these patients had pre-operative scores of 100 and the remaining three patients had scores ranging from 50 to 87.5. Nine patients had good pre-operative visual acuity in the better eye with all but one patient achieving good post-operative acuity in the better eye. Of the seventeen patients who lost visual function, twelve patients had pre-operative VF-14 scores of 80 or more and 86% achieved good post-operative visual acuity in the better eye. There were no differences in age, sex or the presence of ocular comorbidity amongst those patients who gained, lost, or did not change visual function at 12 months after surgery.

5.1 Gains in Visual Function at 4 months

The improvement in visual function by 4 months after surgery was also demonstrated in the group of patients that did not achieve a good visual acuity outcome (n=40). The

mean change in visual function in this group was 16.1 (s.d. 20.2; 95% C.I. 9.7 to 22.6) and compared to their pre-operative values, this was a significant gain (paired t-test and non-parametric tests gave 2-tailed p-values < 0.001). No significant differences in the mean gain in visual function was seen between the sub-groups of patients that had a good visual acuity outcome and those that had a poor outcome.

Table 6.7. Change in Visual Function by Visual Acuity Outcome 4 months after surgery

Visual Acuity Outcome		n	* Mean Change in Visual Function (s.d.) 4 Months after Surgery	
Good Outcome	**(6/6 to 6/12)**	228	20.6	(21.1)
Poor Outcome	**(less than 6/12)**	40	16.1	(20.2)
All #		268	19.9	(20.9)

* All were significant changes (gains) compared to mean pre-operative visual function : paired t-test p-values <0.001

No significant differences in mean change were demonstrated between visual acuity outcome groups : $p > 0.05$

Complete data for visual acuity in surgery eye and visual function both before and 4 months after surgery.

5.2 Change in Visual Function between 4 and 12 months

86 patients had second eye surgery performed between 4 and 12 months. As shown in Table 6.8, no significant mean change in visual function was observed between 4 and 12 months in those patients that had surgery to their first eye only. Significant mean change in visual function was observed between 4 and 12 months in those patients that had had surgery to the second eye during this interval.

Table 6.8 Change in Visual Function between 4 and 12 months after surgery

	FIRST EYES only by 12 months n = 192	BOTH EYES by 12 months n = 86
Mean Visual Function Score (s.d.)		
At 4 months :	89.3 (17.0)	88.3 (16.0)
At 12 months :	90.1 (15.9) *	93.4 (10.2) **

* no significant change between 4 and 12 months, paired t-test p-value = 0.35

** significant change between 4 and 12 months, paired t-test p-value < 0.001

6. RESPONSIVENESS TO CHANGE

The effect size for the VF-14 after cataract surgery were generally higher when computed using the mean scores than with median scores. At 4 months effect size was 0.89 when computed using the mean score. This represents a high responsiveness to change in the assessment of visual function after surgery. When the median change in score was used, the effect size was moderate at 0.50.

The VF-14 was highly responsive to change 12 months after cataract surgery having an effect size of 1.02 (with mean change in score). When the median change in score was used effect size was moderate (0.65). Effect sizes were higher when second eye surgery had been performed - 1.5 for surgery to both eyes compared to 0.85 for surgery to one eye only (1.02 v 0.5 respectively, if median change was used).

7. DISCUSSION OF FINDINGS

The VF-14 was found to be a valid (criterion validity) and reliable (internal consistency) instrument to assess visual function in everyday activities that were dependent on vision, amongst cataract patients.

The pre-operative VF-14 scores in this sample of cataract patients ranged from the minimum to the maximum possible score, with a wide variation in the mean VF-14 score for any given sub-group considered. There are no available data for VF-14 scores amongst the population of this age group (50 years and over) for comparison and assessment of the level of reduced function experienced by cataract patients above that experienced by persons of a similar age group who do not have cataract. The wide spread of scores suggested that a variety of factors may be influencing the reported visual functioning.

Cataract extraction improved visual function (as measured by the VF-14). A mean gain in VF-14 scores was demonstrated both in the short term (4 months after surgery) and long term (at 12 months after surgery), compared to pre-operative values. Post-operatively, at least 80% of patients achieved VF-14 scores of 80 or more, with at least a third of all patients achieving the maximum score of 100. Since data on visual function in a population of 50 years and over is not yet available, it is not possible to conclude that this level of achievement (scores of 80 or more), after surgery is within the range of visual function expected amongst this age group.

The mean gains in visual function observed at 4 months were maintained at one year in those patients that had surgery to one eye only. Those patients that proceeded to have second eye surgery between 4 and 12 months of surgery to the first eye, demonstrated additional mean gain in visual function by 12 months. Significant mean gain in visual function were also observed in the sub-group of patients that did not achieve good visual acuity outcome.

Large effect sizes were observed [125], indicating that the VF-14 as an index of visual functioning was responsive to change and that the observed change was likely to be clinically important also. [157][158][159][160]

It was unlikely that the observed changes in visual function score were due to a placebo effect because of the magnitude of the observed changes and the effect sizes, As the patient interview was conducted at sufficiently long intervals of 4 and 8 months of one another, it was also unlikely for the magnitude of the observed change to have been due to a learning effect as a consequence. However as there was no control group of cataract patients that did not go on to have surgery for comparison, some influence from these effects cannot be completely overlooked.

8. SUMMARY OF FINDINGS

The key findings relating to visual function in cataract patients are :

- The VF-14 as an index of visual functioning in cataract patients is valid, reliable and responsive to change.

- Visual functioning in everyday activities is affected by cataract in the majority of patients

- Cataract surgery improves visual function

- The mean gains in visual function after surgery to the first eye are maintained at one year

- Additional mean gain in visual function were achieved by second eye surgery

- Mean gains in visual function were also achieved in patients with a poor visual acuity outcome

Chapter 7.

THE CATARACT OUTCOME STUDY : RESULTS QUALITY OF LIFE

1. INTRODUCTION

This chapter will present the findings related to the quality of life associated with cataract and the impact surgery may have on this.

The measures of quality of life used in this study were the Sickness Impact Profile (SIP) and the Vision-Related Sickness Impact Profile (VR-SIP). Whilst it was assumed that the reported validity and reliability of the SIP would also apply to UK patients, neither the SIP nor the VR-SIP have been used before in the UK for cataract patients. The criterion validity of the SIP and VR-SIP are presented first. Pre-operative and post-operative findings are then presented as follows :

- a description of quality of life before surgery and 4 and 12 months after surgery
- a description of the change in quality of life after surgery
- the responsiveness of the SIP and VR-SIP to change after surgery

2. CRITERION VALIDITY OF THE SIP AND VR-SIP

Table 7.1 presents the correlation matrix of pre-operative SIP and VR-SIP scores with other pre-operative variables. Spearman coefficients are presented, but Pearson correlation coefficients provided similar findings.

SIP scores correlated better with age and with other measures of health such as the comorbidity "bothersome" score and comparative assessments of health, and visual functioning, and correlated poorly with global assessments of vision.

VR-SIP scores were correlated highly with visual functioning. VR-SIP scores correlated better with other vision related variables such as global assessments of vision, better eye visual acuity; and poorly with other measures of health. No significant correlation with age was observed.

Both SIP and VR-SIP had correlations of a similar order with better eye visual acuity, and both correlated poorly with visual acuity in the surgery eye.

Table 7.1 Correlation Matrix of Pre-Operative SIP Scores with other Pre-Operative measures of health, demography, visual acuity and visual function : SPEARMAN Correlation Coefficients

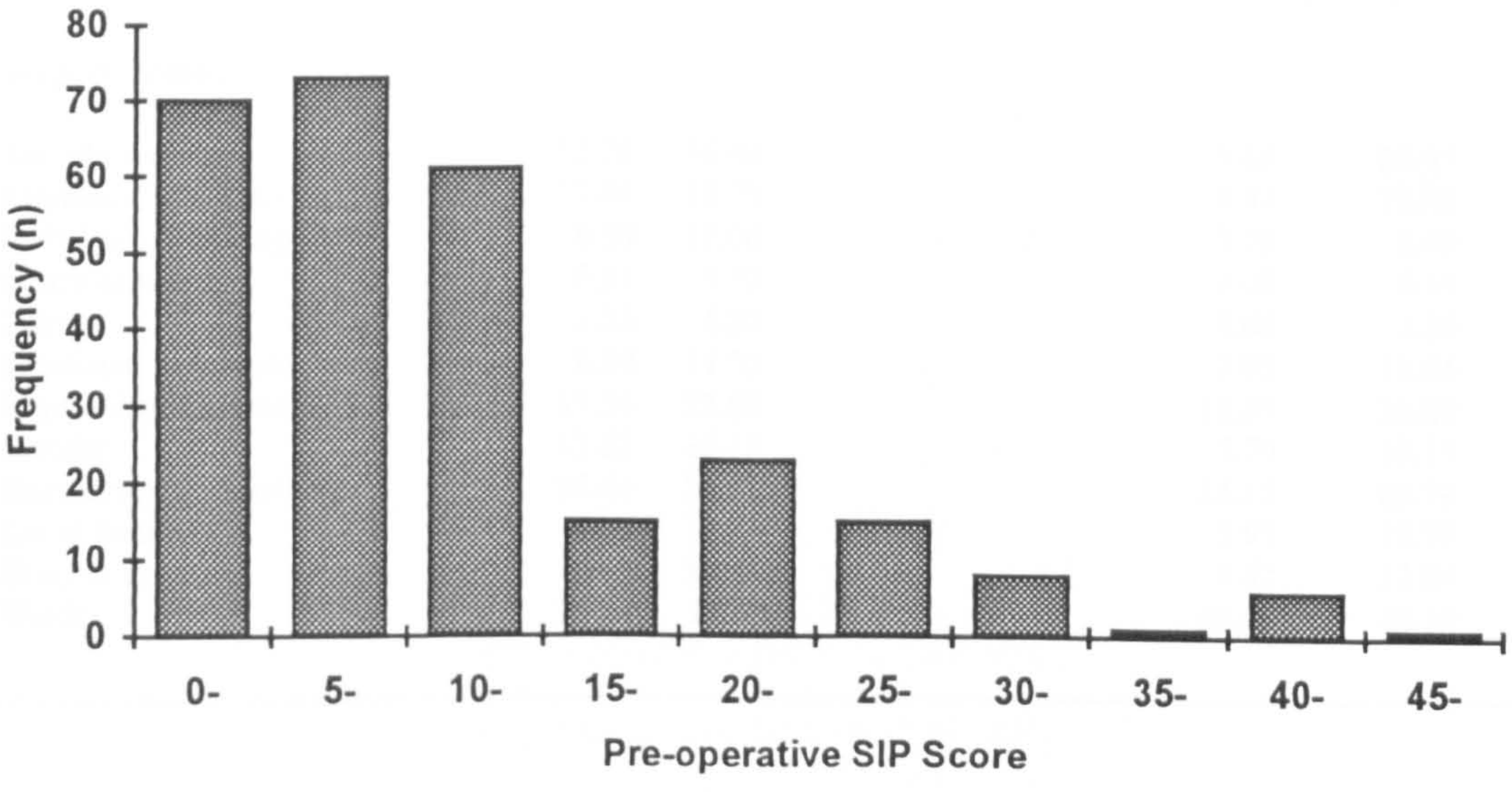
	SIP	VR-SIP	Age	Comorbidity	C1	C2	BVHI	S-Eye	VF-14	A1	A2
SIP	-	-	-	-	-	-	-	-	-	-	-
VR-SIP	0.4037	-	-	-	-	-	-	-	-	-	-
Age	0.3541	* -0.0494	-	-	-	-	-	-	-	-	-
Comorbidity											
"Bothersome Score"	0.5762	0.2256	0.1369	-	-	-	-	-	-	-	-
Comparative Assessment of Health :											
C1	0.4593	0.1613	* -0.0268	* 0.5524	-	-	-	-	-	-	-
C2	0.3564	* 0.083	-0.2351	* 0.3427	0.5509	-	-	-	-	-	-
Visual Acuity :											
Better Eye - BVHI	-0.3359	-0.3391	-0.3135	-0.1406	* -0.0028	* 0.0135	-	-	-	-	-
Surgery Eye - S-Eye	-0.1818	-0.1696	* -0.0959	* -0.1009	* 0.0070	* 0.0091	0.3949	-	-	-	-
Visual Function : VF-14 Score	-0.3713	-0.7054	* -0.0109	-0.2711	-0.1380	-0.1096	0.4763	0.2065	-	-	-
Global Assessment of Vision :											
"Trouble with Vision" - A1	0.2200	0.4833	* -0.0611	0.2517	0.1422	0.1154	-0.3773	-0.1919	-0.5553	-	-
"Satisfaction with Vision" - A2	0.2155	0.3978	* -0.0530	0.1790	0.1753	0.1143	-0.3252	-0.1884	-0.4880	0.5445	-

* - Spearman Correlation Coefficients not reaching statistical significance, $p > 0.05$

3. PRE-OPERATIVE QUALITY OF LIFE

The distribution of pre-operative scores for both SIP and VR-SIP were highly skewed towards the lower scores (less reported handicap), and are presented below in Figures 8.1 and 8.2 respectively. No statistical transformation was effective in normalising either of these distributions, so the untransformed pre-operative SIP and VR-SIP scores were used in all further analysis. The category scores were also highly skewed distributions towards the lower scores (less reported handicap). Given this, means (and standard deviations) are reported to be consistent and comparable with published literature, but medians (with inter-quartile range) are also provided as these provide a further, and perhaps more appropriate description of the distributions.

Figure 7.1 Distribution of Pre-operative SIP Score. n = 273



The mean SIP score on admission was 11.9 (s.d. 9.7), and the median was 9.5 (inter-quartile range 10.2), with scores ranging from 0 to 47. 8 patients (2.9%) had scores of zero pre-operatively, indicating no health related handicap, and so these patients

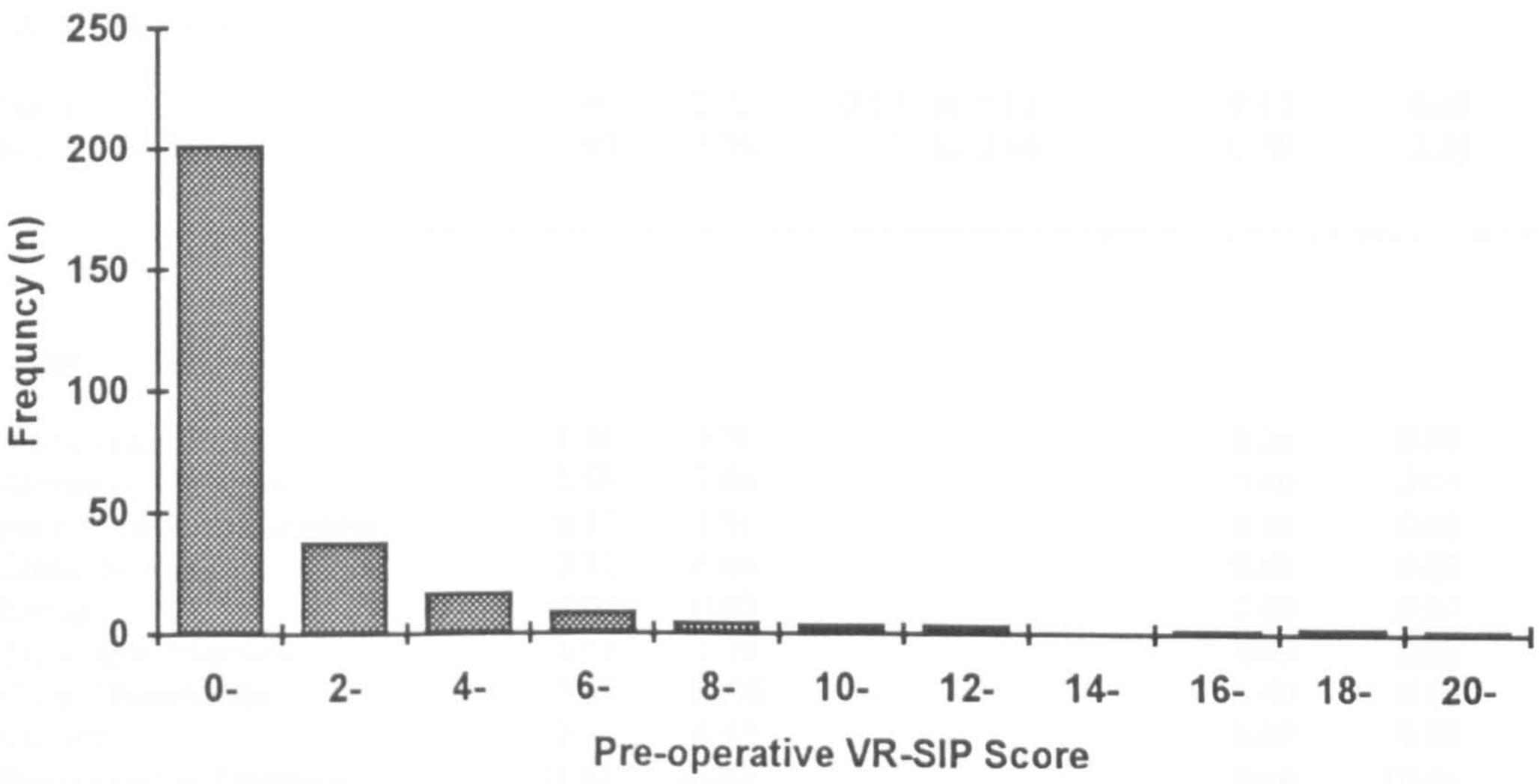
could not demonstrate any gain (benefit) after cataract surgery. As seen in Table 7.2, the categories with the highest scores were recreation and pastimes, work, and home management.

Table 7.2. Pre-Operative Sickness Impact Profile (SIP) Score. N=273

Scores	Mean Score	s.d.	95% C.I. for Mean Score	Median	Inter-Quartile Range
Total Score	11.88	9.66	10.72 to 13.03	9.46	10.25
Dimension Scores :					
Physical	9.96	11.54	8.58 to 11.33	5.75	12.40
Psychosocial	9.30	10.07	8.09 to 10.49	6.33	11.74
Category Score :					
Ambulation	15.78	16.40		9.86	24.47
Alertness Behaviour	13.06	18.70		9.41	19.20
Body Care & Management	6.59	11.06		3.20	8.49
Communication	6.21	9.32		0.00	9.63
Eating	3.35	5.27		0.00	5.25
Emotional Behaviour	8.29	14.05		0.00	11.06
Home Management	**17.94**	**22.51**		**10.33**	**26.20**
Mobility	12.52	15.13		7.79	19.19
Recreation & Pastimes	**26.44**	**21.88**		**24.17**	**32.70**
Social Interaction	9.27	10.89		5.93	12.76
Sleep & Rest	13.62	18.96		9.82	21.84
Work	**26.24**	**22.53**		**46.10**	**46.10**

The mean VR-SIP score on admission was 1.9 (s.d. 3.3), and the median was 0.6 (inter-quartile range 2.1), with scores ranging from 0 to 21.9. 41% (n=112/273), of patients had a score of 0. These patients did not attribute any aspect of their quality of life to their vision and could not therefore, demonstrate any gain (benefit) after cataract surgery.

Figure 7.2 Distribution of Pre-operative VR-SIP Score. n = 273



As seen in Table 7.3, recreation and pastimes was the category that had the highest mean score (10.6), indicating greatest handicap attributed to vision, in this area. However as indicated by the mean and inter-quartile range, this category was affected in about 25% of patients (in the highest quartile).

Table 7.3. Pre-Operative Vision-Related Sickness Impact Profile (VR-SIP) Score. n =273.

Scores	Mean Score	s.d.	95% C.I. for Mean Score	Median	Inter-Quartile Range
Total VR-SIP Score :	1.85	3.32	1.46 to 2.25	0.57	2.10
Dimension Scores :					
Physical	0.86	2.22	0.59 to 1.12	0.00	0.00
Psychosocial	1.99	3.96	1.52 to 2.46	0.00	2.28
Category Score :					
Ambulation	1.14	4.38		0.00	0.00
Alertness Behaviour	2.68	7.06		0.00	0.00
Body Care & Management	0.27	1.16		0.00	0.00
Communication	3.22	6.69		0.00	0.00
Eating	0.00	0.00		0.00	0.00
Emotional Behaviour	1.63	5.70		0.00	0.00
Home Management	3.48	11.96		0.00	0.00
Mobility	2.16	6.53		0.00	0.00
Recreation & Pastimes	**10.61**	**15.34**		**0.00**	**19.43**
Social Interaction	1.17	3.40		0.00	0.00
Sleep & Rest	2.64	9.57		0.00	0.00
Work	0.82	5.71		0.00	0.00

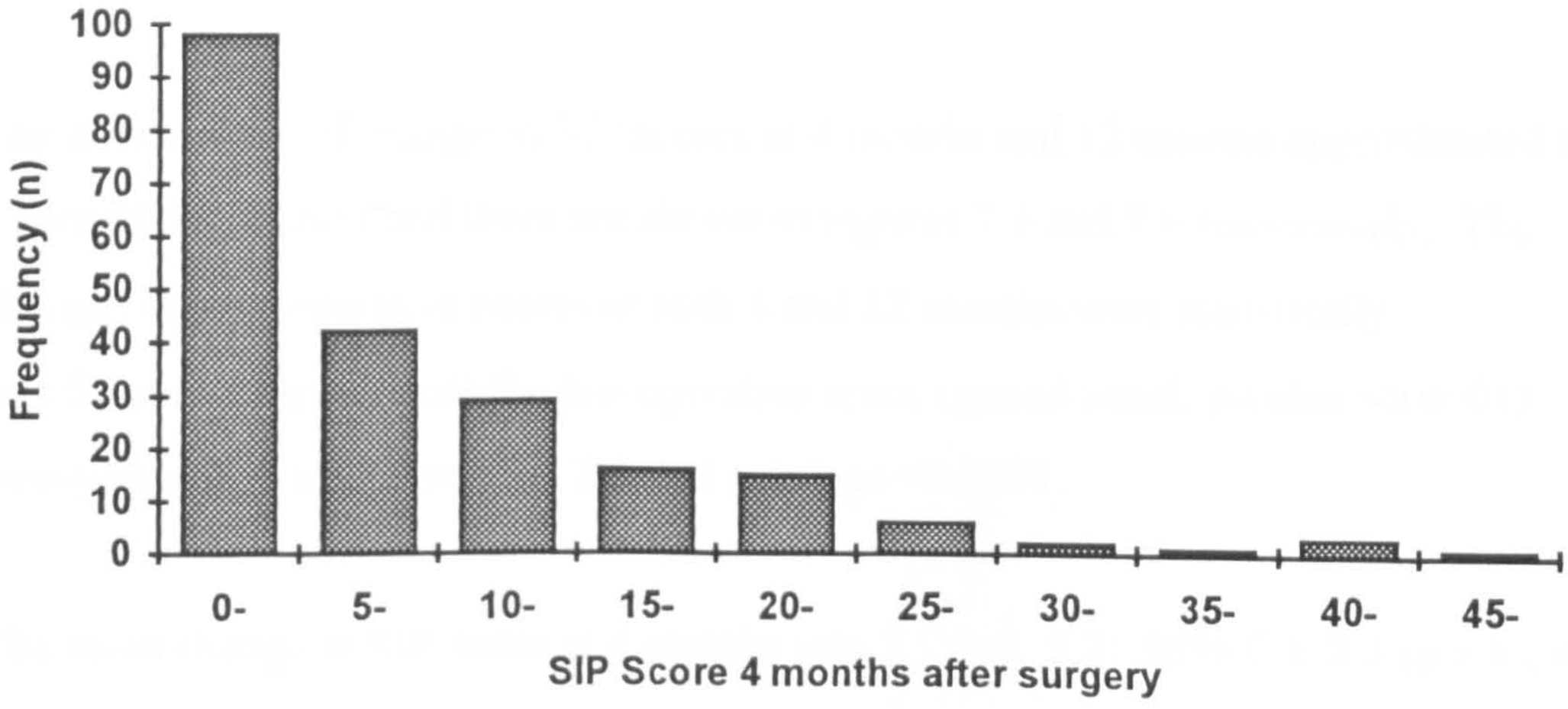
4. POST-OPERATIVE QUALITY OF LIFE

There were 213 patients with complete data that were available for analysis at 4 months and 217 patients at 12 months after surgery.

4.1 Post-operative SIP Scores

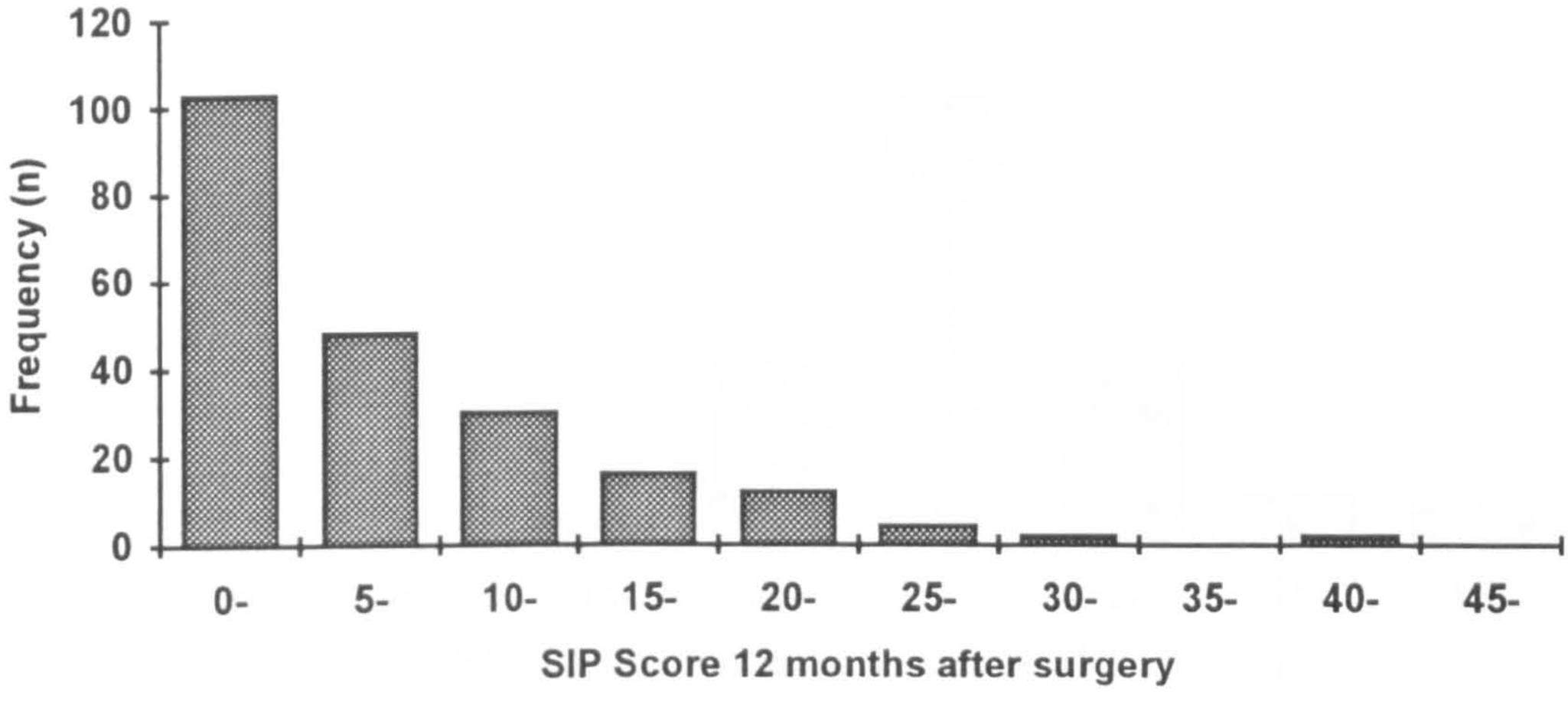
The distributions of post-operative scores for SIP at 4 and 12 months after surgery (Figures 7.3 and 7.4 respectively), were both highly skewed towards the lower scores, and no statistical transformation was effective in normalising these distributions.

Figure 7.3 Distribution of SIP Scores 4 Months after Surgery. n = 213



The mean SIP score at 4 months was 9.0 (s.d. 8.7), the median was 5.9 (inter-quartile range 9.9), with scores ranging from 0.4 to 45.8. The mean SIP score at 12 months was 8.1 (s.d. 7.7), the median was 5.3 (inter-quartile range 9.0) and scores ranged from 0.4 to 44.7.

Figure 7.4 Distribution of SIP Scores 12 Months After Surgery
n = 217



4.2 Change in SIP Score (compared to pre-operative scores)

The distributions of change in SIP scores at 4 months and 12 months approximated to a normal distribution and these are shown in Figures 7.5 and 7.6 respectively. The changes in post-operative scores at both 4 and 12 months were statistically significantly different from the pre-operative score (paired t-test, p-value <0.0001). Non-parametric tests also gave 2-tailed p-values <0.0001.

The mean change in SIP score at 4 months was 3.1 (s.d. 5.3; 95% C.I. 2.3 to 3.8), the median change was 3.1 (inter-quartile range 5.24), with change in scores ranging from -19.9 to 19.8. The mean change in SIP score at 12 months after surgery was 2.5 (s.d. 4.9; 95% C.I. 1.9 to 3.2). The median change was 2.7 (inter-quartile range = 4.9), with change in score ranging from -20.2 to 19.0.

Figure 7.5 Distribution of CHANGE in SIP Scores
4 Months after surgery. n = 213

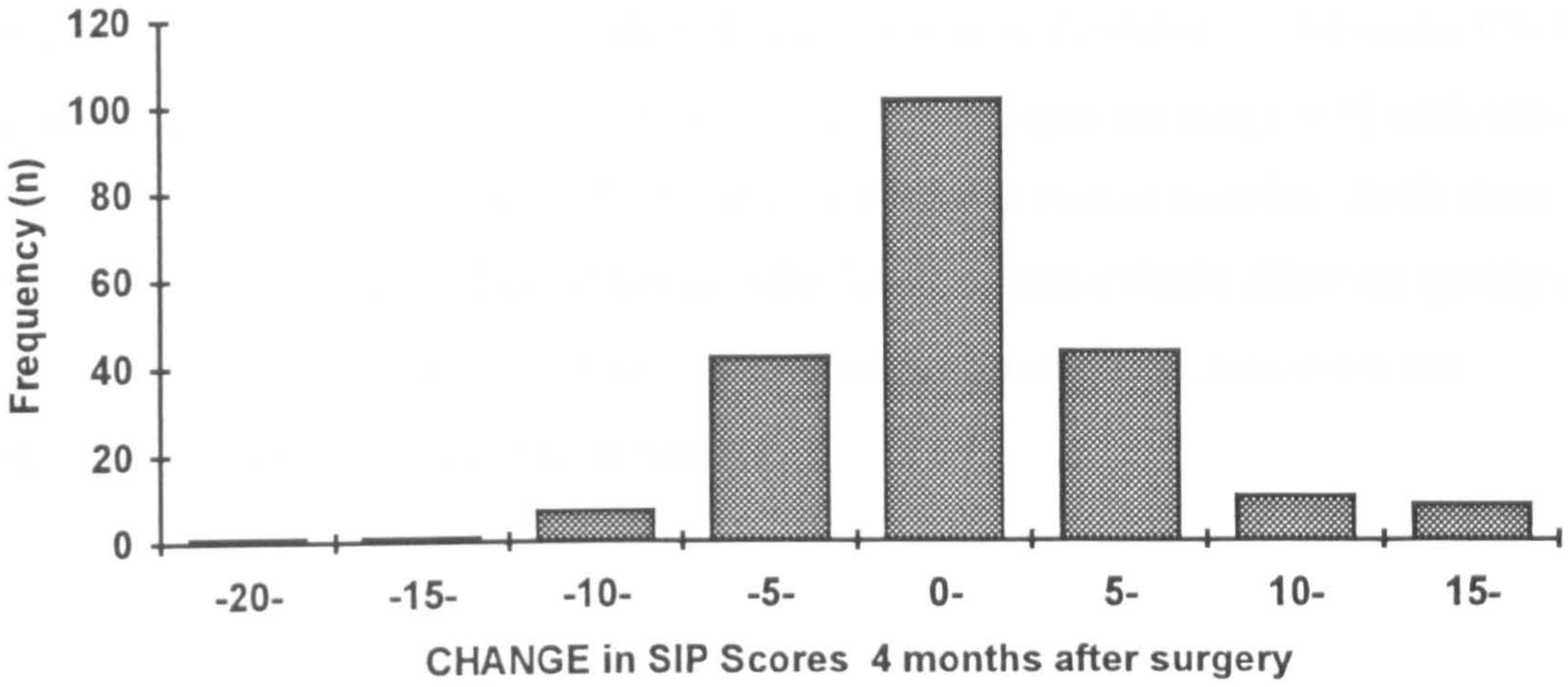
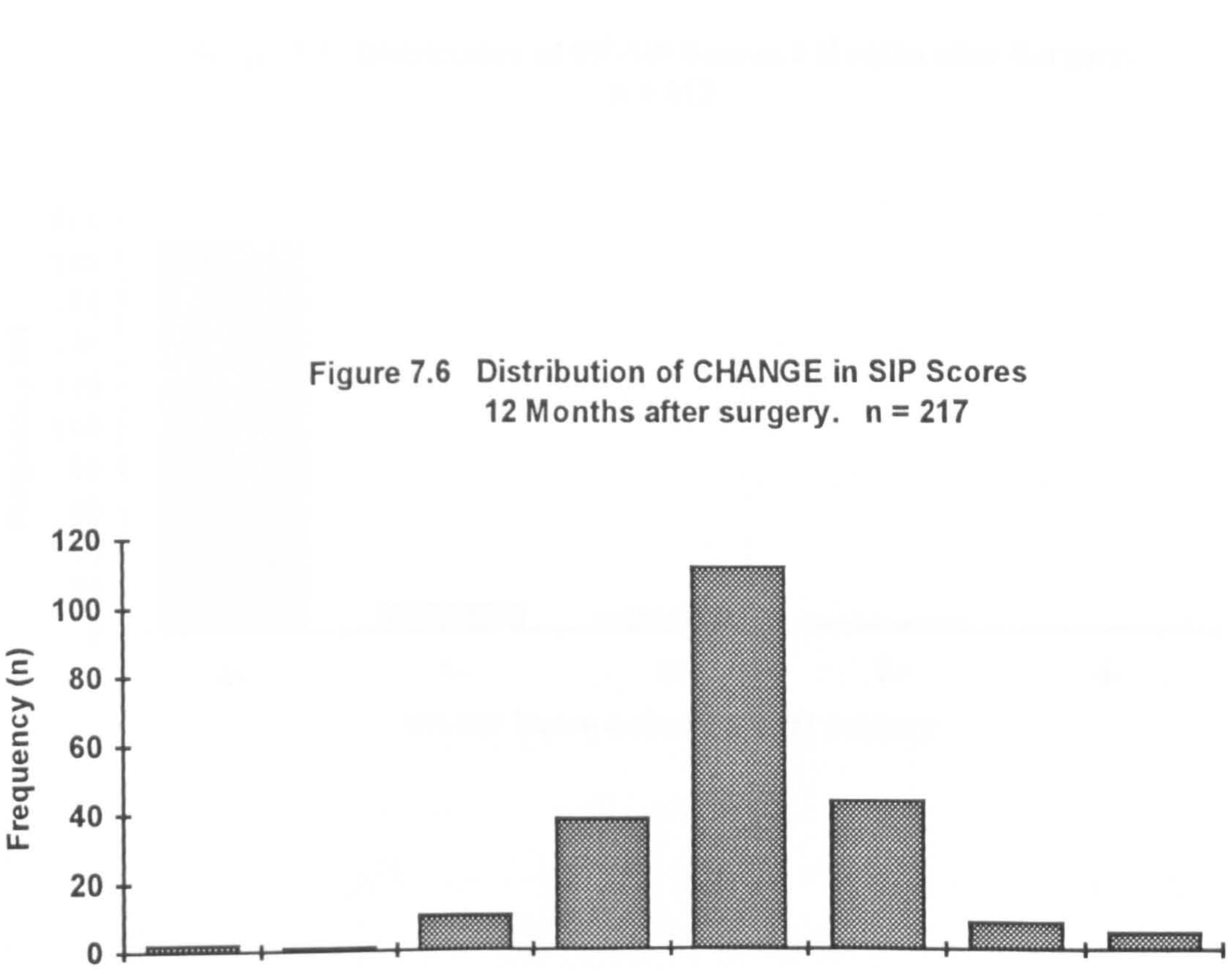


Figure 7.6 Distribution of CHANGE in SIP Scores
12 Months after surgery. n = 217



4.3 Post-Operative VR-SIP Scores

The mean VR-SIP score at 4 months was 0.3 (s.d. 0.7), the median was 0 (inter-quartile range 0.4), and scores ranged from 0 to 4.2. 156 (73%) patients had a score of zero - quality of life was not affected due to vision at this time. The mean VR-SIP score at 12 months was 0.19 (s.d. 0.5), median 0 (inter-quartile range = 0) with scores ranging from 0 to 3.3. 178 (82%) patients scored 0 at twelve months. Both these distributions were highly skewed towards the lower scores of little affect on quality of life and are shown in Figures 7.7 and 7.8. Statistical transformations were not effective in normalising these distributions.

Figure 7.7 Distribution of VR-SIP Scores 4 Months after Surgery.
n = 213

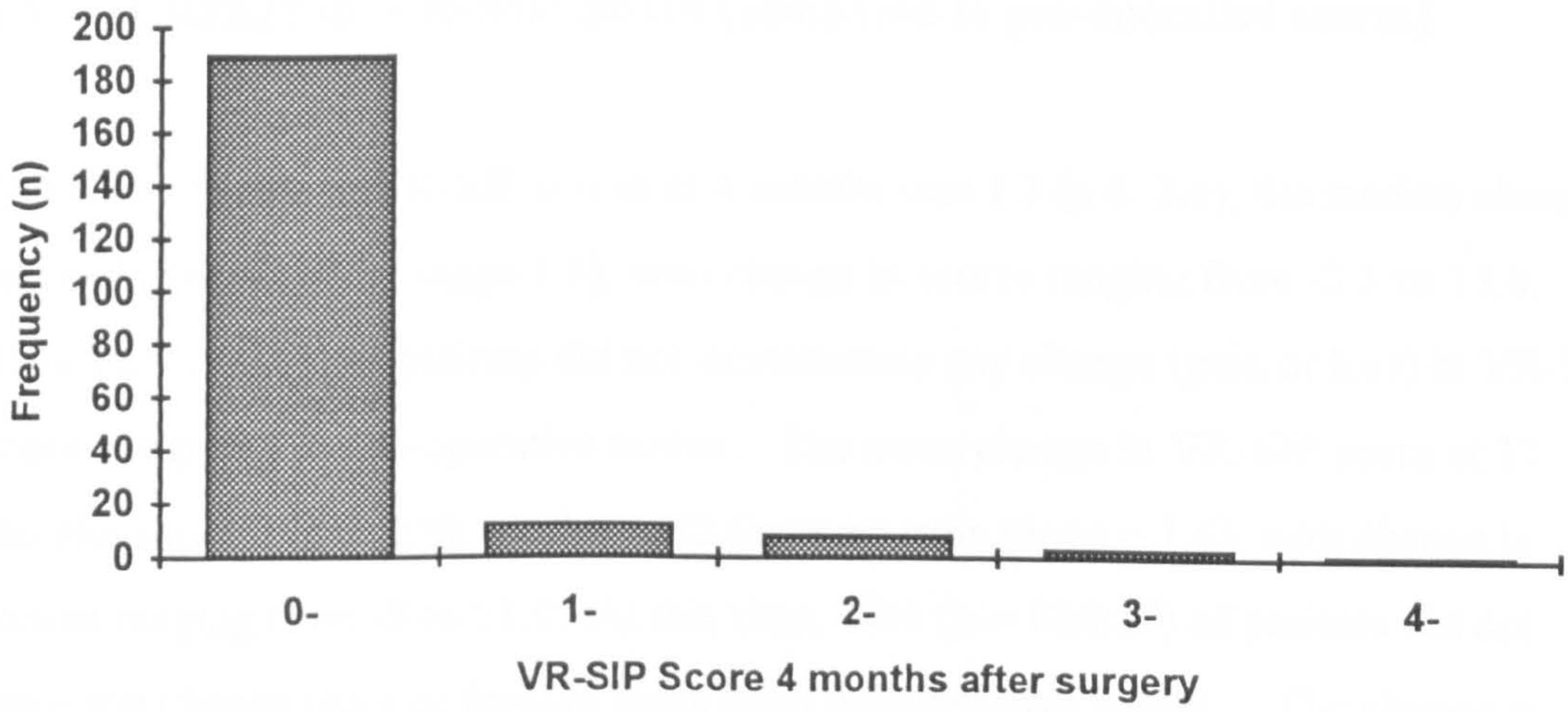
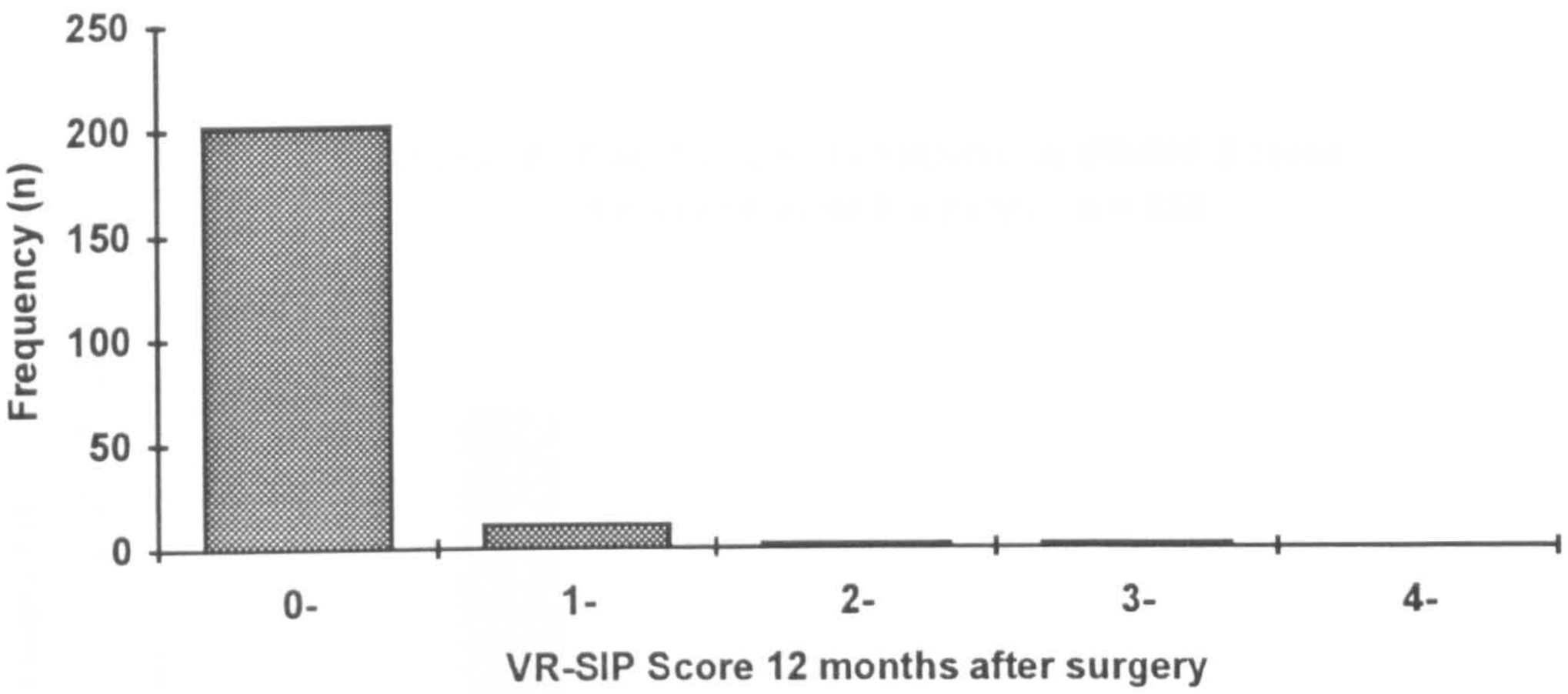


Figure 7.8 Distribution of VR-SIP Scores 12 Months after Surgery.
n = 217



4.4 Change in VR-SIP Score (compared to pre-operative scores)

The mean change in VR-SIP scores at 4 months was 1.3 (s.d. 2.6), the median change was 0.4 (inter-quartile range 1.5), with change in scores ranging from -3.3 to 13.6. 35% (n = 74/213) of patients did not demonstrate any change (gain or loss) in VR-SIP score compared to pre-operative scores. The mean change in VR-SIP score at 12 months was 1.5 (s.d. 2.9), median 0.52 (inter-quartile range = 1.6), with change in scores ranging from -3 to 21.9. At this time, 38% (n = 82/217) of patients did not have any change (gain or loss) in score from pre-operative values. The change in VR.-SIP score at both 4 and 12 months after surgery was statistically significant from pre-operative values (paired t-test, p-value <0.001). Non-parametric tests also gave 2-tailed p-values <0.001.

The distributions of change in VR-SIP scores at these times were both skewed towards the lower scores and are shown in Figures 7.9 and 7.10, and statistical transformations were not effective in normalising them.

Figure7.9 Distribution of CHANGE in VR-SIP Scores 4 Months after Surgery. n = 213

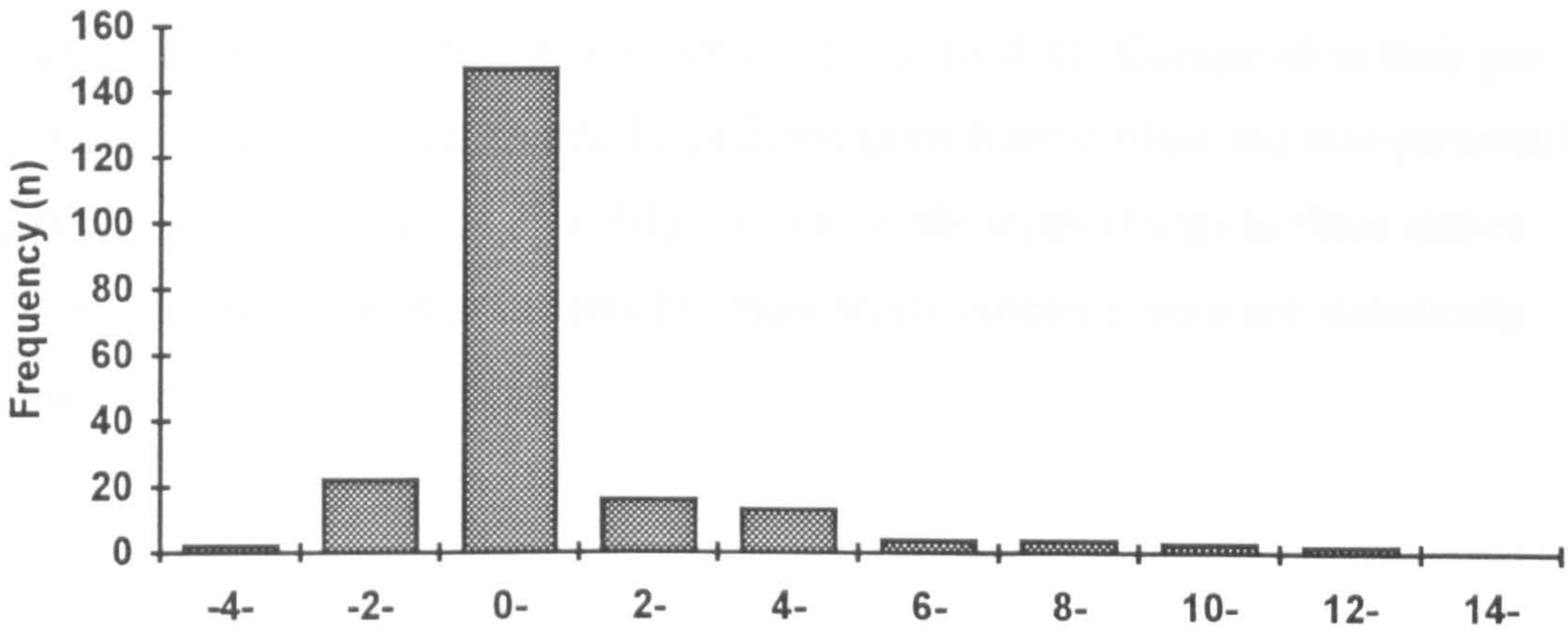
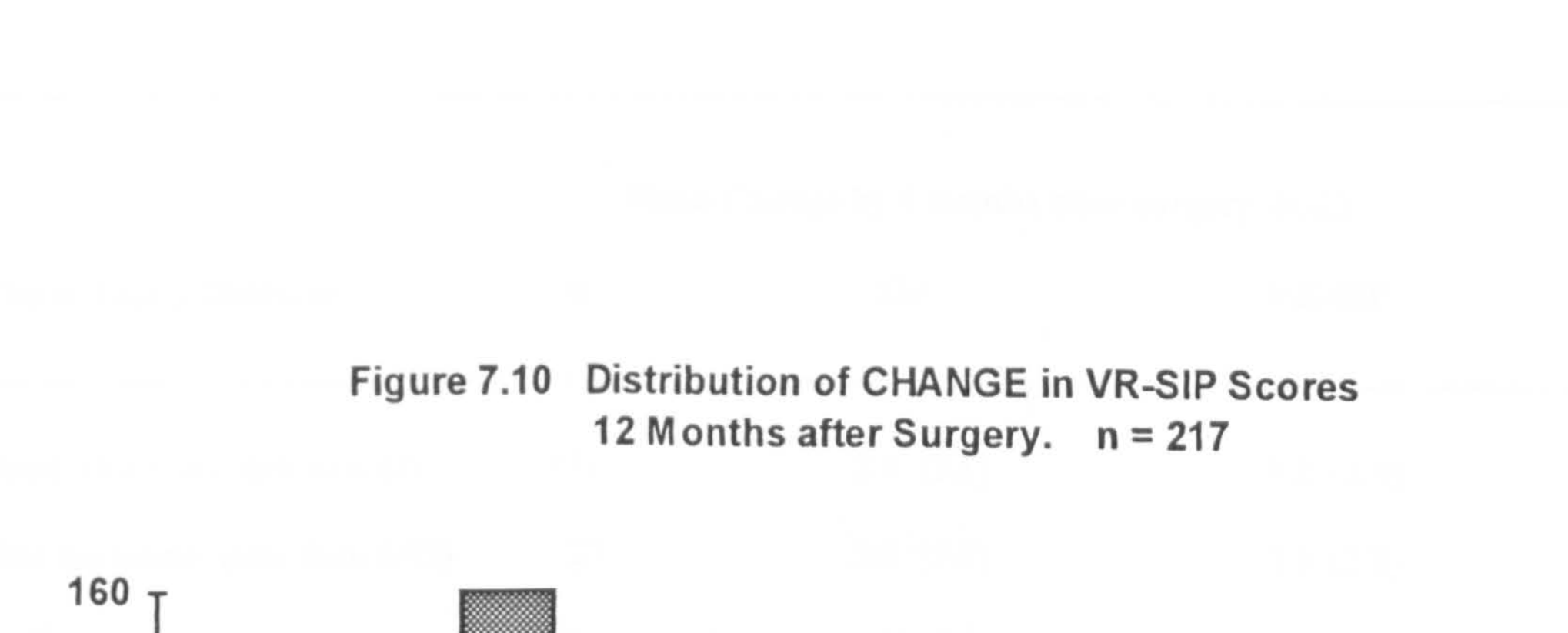


Figure 7.10 Distribution of CHANGE in VR-SIP Scores 12 Months after Surgery. n = 217



4.5 Change in Quality of Life at 4 Months and Visual Acuity Outcome

The changes in quality of life by 4 months after surgery were also demonstrated in the group of patients that did not achieve a good visual acuity outcome (n=27 with complete SIP and VR-SIP at 4 months). As seen in Table 7.4, the mean change in SIP scores in this group was 5.8 (s.d. 5.8; 95% C.I. 3.6 to 8.1), and the mean change in VR-SIP scores was 2.9 (s.d. 3.8; 95% C.I. 1.3 to 4.4). Compared to their pre-operative values, these represented significant gains (paired t-test and non-parametric tests gave 2-tailed p-values < 0.001). However, the mean change in these scores between the sub-groups of patients by visual acuity outcome were not statistically significant.

Table 7.4. Change in Quality of Life by Visual Acuity Outcome - 4 months after surgery

		* Mean Change by 4 months after surgery (s.d.)	
Visual Acuity Outcome	**n**	**SIP**	**VR-SIP**
Good Outcome (6/6 to 6/12)	151	2.8 (5.1)	1.2 (2.4)
Poor Outcome (less than 6/12)	27	5.8 (5.8)	2.9 (3.8)
All #	178	3.2 (5.2)	1.4 (2.7)

* All were significant gains compared to pre-operative values : paired t-test p-values <= 0.001

No significant differences in mean change were demonstrated between visual outcome groups: un-paired t-test $p>0.05$

Complete data for visual acuity in the surgery eye, SIP, and VR-SIP, both before surgery and at 4 months

4.6 Change in Quality of Life Between 4 and 12 Months after Surgery

Of the 86 patients that had cataract surgery to their second eye between 4 and 12 months, 72 patients had complete SIP and VR-SIP at both 4 and 12 months.

As shown in Table 7.5, no significant mean changes in quality of life scores (SIP and VR-SIP) were observed between 4 and 12 months after surgery in those patients that had surgery to their first eye only. Those patients that had surgery to the second eye (between 4 and 12 months of surgery to the first eye), had significant mean changes in both SIP and VR-SIP scores at one year.

Table 7.5. Change in Quality of Life between 4 and 12 months after surgery

	FIRST EYES only by 12 Months		BOTH EYES by 12 Months	
	4 Month Score mean (s.d.)	12 Month Score mean (s.d.)	4 Month Score mean (s.d.)	12 Month Score mean (s.d)
Quality of Life #:				
Sickness Impact Profile (SIP)	8.00 (7.9)	8.50 (8.2)	9.10 (8.3)	7.30 (6.8) **
Vision-Related SIP	0.33 (0.8)	0.22 * (0.6)	0.26 (0.6)	0.13 (0.3) **

* significant gain between 4 and 12 months for first eye surgery only, paired t-test p-value = 0.02

** significant gain between 4 and 12 months - when second eye surgery performed during this interval, paired t-test p-value <0.05

\# SIP and VR-SIP : first eyes n=145 ; second eyes n=72

5. Responsiveness to Change

This is presented in terms of effect sizes for overall, dimensions and categories of SIP and VR-SIP in terms of both the mean change and median change in score at 4 and 12 months.

The overall effect size for SIP at 4 months after cataract surgery was 0.33 and at 12 months the effect size was 0.31 and were of a similar order when computed using the mean scores (Tables 7.6 and 7.7). Effect sizes were higher for the psychosocial dimension than for the physical dimension.

The overall effect sizes for VR-SIP were lower than for SIP. At 4 months after surgery effect size for VR-SIP was 0.21 and at 12 months effect size was 0.28 and were generally lower than those computed by the mean scores. However as the VR-SIP scores were highly skewed, effect size is likely to better described using the median scores. Effect sizes for the physical and psychosocial dimensions were 0. (Tables 7.8 and 7.9.)

Table 7.6. Effect Size for Change in SIP Score at 4 Months. N=213

	PRE-OPERATIVE SIP SCORE				CHANGE IN SIP SCORE AT 4 MONTHS		EFFECT SIZE *	EFFECT SIZE **
	mean	s.d	median	I-q range	mean	median		
Overall Score	12.06	9.21	10.07	9.52	3.05	3.10	0.33	0.33
Physical Dimension Score	9.82	11.14	6.20	11.07	0.48	0.22	0.04	0.02
Psychosocial Dimension Score	9.31	9.93	6.47	11.74	3.11	1.90	0.31	0.16

* Effect Size = mean change in score at 4 months / s.d. of pre-operative score
** Effect Size = median change at 4 months / inter-quartile range pre-operatively

Table 7.7. Effect Size for Change in SIP Score at 12 Months. N=217

	PRE-OPERATIVE SIP SCORE				CHANGE IN SIP SCORE AT 12 MONTHS		EFFECT SIZE *	EFFECT SIZE **
	mean	s.d	median	I-q range	mean	median		
Overall Score	10.62	8.42	8.94	8.89	2.52	2.72	0.30	0.31
Physical Dimension Score	8.72	10.36	5.42	11.20	0.20	0.00	0.02	0.00
Psychosocial Dimension Score	8.10	8.37	5.84	8.94	3.12	1.47	0.37	0.16

* Effect Size = mean change in score at 12 months / s.d. of pre-operative score
** Effect Size = median change at 12 months / inter-quartile range pre-operatively

Table 7.8. Effect Size for Change in VR-SIP Score at 4 months. N=213

	PRE-OPERATIVE VR-SIP SCORE				CHANGE IN VR-SIP SCORE AT 4 MONTHS		EFFECT SIZE *	EFFECT SIZE **
	mean	s.d	median	i-q range	mean	median		
Overall Score	1.61	2.68	0.57	1.79	1.27	0.38	0.47	0.21
Physical Dimension Score	0.68	1.79	0.00	0.00	0.50	0.00	0.28	0.00
Psychosocial Dimension Score	1.78	3.61	0.00	2.04	1.62	0.00	0.45	0.00

* Effect Size = mean change in score at 4 months / s.d. of pre-operative score

** Effect Size = median change at 4 months / inter-quartile range pre-operatively

Table 7.9. Effect Size for Change in VR-SIP Score at 12 months. N=217

	PRE-OPERATIVE VR-SIP SCORE				CHANGE IN VR-SIP SCORE AT 12 MONTHS		EFFECT SIZE *	EFFECT SIZE **
	mean	s.d	median	i-q range	mean	median		
Overall Score	1.65	2.94	0.57	1.88	1.46	0.52	0.50	0.28
Physical Dimension Score	0.71	1.82	0.00	0.00	0.65	0.00	0.36	0.00
Psychosocial Dimension Score	1.78	3.68	0.00	2.04	1.61	0.00	0.44	0.00

* Effect Size = mean change in score at 12 months / s.d. of pre-operative score

** Effect Size = median change at 12 months / inter-quartile range pre-operatively

Since effect sizes post-operatively were small and of a similar order at both 4 and 12 months for both instruments, further examination of effect size by categories was performed for 4 month scores only. As both the pre-operative, and the change in category scores were highly skewed, effect size by categories are probably better described by those computed with median scores and inter-quartile range.

The SIP categories with the highest effect sizes (for gain), were work, and recreation and pastimes. The eating category demonstrated a loss in function after surgery (indicated by the negative sign). (Table 7.10.)

Individual category scores for VR-SIP were not responsive to change after cataract surgery, having effect sizes of zero (Table 7.11). Patients that had a pre-operative VR-SIP score of zero (who could not demonstrate any gain), were then excluded and the findings are presented in Table 7.12. The only category that demonstrated an effect size was that for recreation and pastimes (0.5). All the remaining categories had effect sizes of zero. The overall effect size for gain although slightly higher, was still poor at 0.4, effect size for the physical dimension was 0, and that for the psychosocial score was 0.3.

Table 7.10. SIP Scores and Change by 4 Months : Overall, Dimension and Category Scores

SIP Category	PRE-OPERATIVE SCORE Mean	s.d.	Median	Inter-quartile range	CHANGE IN SCORE AT 4 MONTHS Mean	s.d.	Median	Inter-quartile range	EFFECT SIZE *	EFFECT SIZE **
Ambulation	15.0	15.5	9.9	24.2	-0.6	9.0	0.0	8.3	-0.0	0.0
Alertness Behaviour	13.4	19.1	8.7	19.2	4.9	15.0	0.0	9.8	0.3	0.0
Body Care & Management	6.5	10.3	3.2	8.5	0.7	5.8	0.0	3.0	0.1	0.0
Communication	5.9	9.5	0.0	9.6	2.6	8.0	0.0	9.5	0.3	0.0
Eating	3.4	5.5	0.0	5.3	-9.1	15.2	-2.7	16.2	-1.7	-0.5
Emotional Behaviour	8.6	14.3	0.0	11.1	3.7	10.8	0.0	8.8	0.3	0.0
Home Management	16.4	19.8	8.7	26.2	1.9	15.3	0.0	9.3	0.1	0.0
Mobility	12.2	14.7	8.5	19.2	1.8	11.6	0.0	8.3	0.1	0.0
Recreation & Pastimes	25.9	21.6	23.2	32.8	18.4	19.1	16.8	31.0	0.8	0.5
Social Interaction	9.3	11.4	5.9	12.6	2.4	9.0	0.0	5.9	0.2	0.0
Sleep and Rest	13.9	19.2	9.8	22.0	5.4	17.4	0.0	12.0	0.3	0.0
Work	29.8	21.7	46.1	46.1	15.9	25.1	35.9	40.6	0.7	0.8
Total	12.0	9.5	9.8	10.0	3.1	5.3	3.0	5.4	0.3	0.3
Physical	9.6	10.9	5.9	12.5	0.6	5.2	0.2	4.3	0.1	0.0
Psychosocial	9.4	10.3	6.2	11.9	3.3	7.3	1.8	5.8	0.3	0.1

Effect Size * = mean change / s.d. of pre-operative score
Effect Size ** = median change / inter-quartile range of pre-operative score

Table 7.11. VR-SIP Scores and Change by 4 Months: Overall, Dimension and Categroy Scores

VR-SIP Category	Pre-Operative VR-SIP Score				Change in VR-SIP Score at 4 months				Effect Size *	Effect Size **
	mean	s.d.	median	I-q range	mean	s.d.	median	I-q range		
ambulation	0.9	3.1	0.0	0.0	0.8	3.2	0.0	0.0	0.2	0.0
alertness behaviour	2.4	6.8	0.0	0.0	2.0	6.8	0.0	0.0	0.3	0.0
body care & management	0.2	1.2	0.0	0.0	0.1	1.4	0.0	0.0	0.1	0.0
communication	2.8	6.1	0.0	0.0	2.0	5.1	0.0	0.0	0.3	0.0
eating	0.0	0.0	0.0	0.0	-0.4	1.6	0.0	0.0	0.0	0.0
emotional behaviour	1.7	5.9	0.0	0.0	1.5	6.0	0.0	0.0	0.3	0.0
home management	2.5	7.5	0.0	0.0	2.5	7.5	0.0	0.0	0.3	0.0
mobility	1.8	5.5	0.0	0.0	1.5	5.3	0.0	0.0	0.3	0.0
recreation & pastimes	10.1	14.5	0.0	0.0	7.7	14.0	0.0	0.0	0.5	0.0
social interaction	1.0	2.8	0.0	0.0	1.0	2.8	0.0	0.0	0.3	0.0
sleep & rest	2.1	8.4	0.0	0.0	1.6	9.4	0.0	0.0	0.2	0.0
work	1.1	6.8	0.0	0.0	1.1	6.8	0.0	0.0	0.2	0.0
total	1.6	2.7	0.6	1.8	1.3	2.6	0.4	1.6	0.5	0.2
vphysical	0.7	1.8	0.0	0.0	0.5	1.8	0.0	0.0	0.3	0.0
vpsychosocial	1.8	3.5	0.0	2.0	1.5	3.4	0.0	0.0	0.4	0.0

* Effect Size = mean change at 4 months / s.d. pre-operative scores

** Effect Size = median change at 4 months / pre-operative inter-quartile range

Table 7.12 VR-SIP Scores and Change by 4 Months : Overall, Dimension and Category Scores
(Excluding patients with Pre-op VR-SIP Score = 0). N=113

VR-SIP Category	Pre-Operative VR-SIP Score				Change in VR-SIP Score at 4 months				Effect Size *	Effect Size **
	mean	s.d.	median	i-q range	mean	s.d.	median	i-q range		
ambulation	1.5	4.0	0.0	0.0	1.3	4.1	0.0	0.0	0.3	0.0
alertness behaviour	4.1	8.4	0.0	0.0	3.4	8.6	0.0	0.0	0.4	0.0
body care & management	0.4	1.5	0.0	0.0	0.2	1.7	0.0	0.0	0.1	0.0
communication	4.7	7.4	0.0	0.0	3.5	6.1	0.0	9.6	0.5	0.0
eating	0.0	0.0	0.0	0.0	-0.6	1.8	0.0	0.0	0.0	0.0
emotional behaviour	2.8	7.4	0.0	0.0	2.6	7.6	0.0	0.0	0.4	0.0
home management	4.1	9.4	0.0	0.0	4.1	9.4	0.0	0.0	0.4	0.0
mobility	3.0	6.9	0.0	0.0	2.5	6.6	0.0	0.0	0.4	0.0
recreation & pastimes	17.1	15.4	14.0	23.2	13.3	15.5	12.1	23.2	0.9	0.5
social interaction	1.6	3.5	0.0	2.5	1.6	3.5	0.0	0.0	0.5	0.0
sleep & rest	3.5	10.7	0.0	0.0	3.2	11.1	0.0	0.0	0.3	0.0
work	1.9	8.8	0.0	0.0	1.9	8.8	0.0	0.0	0.2	0.0
total	2.8	3.0	1.3	3.1	2.3	3.0	1.2	2.6	0.7	0.4
vphysical	1.2	2.3	0.0	0.0	0.9	2.2	0.0	0.0	0.4	0.0
vpsychosocial	3.0	4.1	1.9	4.2	2.6	4.0	1.3	3.9	0.6	0.3

* Effect Size = mean change at 4 months / s.d. pre-operative scores
** Effect Size = median change at 4 months / pre-operative inter-quartile range

6. DISCUSSION OF FINDINGS

The SIP scores provided a measure of the quality of life of pre-operative cataract patients. The VR-SIP scores provided a disease-specific measure of quality of life i.e. a measure of the quality of life affected by vision (vision-related quality of life).

The criterion validity of the instruments were acceptable. The findings indicated that in this sample of cataract patients, both the generic instrument (SIP), and its modification (VR-SIP), function as expected, as presented by their relationships with the other pre-operative variables considered. The SIP correlated best with measures of health and better with visual function than with other measures of visual acuity and visual health. VR-SIP scores correlated best with visual function and measure of visual acuity than with measures of general health.

These instruments provided scores with distributions that were highly skewed towards the lower scores of less reported dysfunction and handicap, particularly in the case of VR-SIP. In this situation, the mean as measure of central tendency and its standard deviation as a measure of the spread of observations about the mean may be misleading. The median (and inter-quartile range) may be more stable in these circumstances as it is less likely to influenced by extreme values. Both were presented but greater emphasis was laid on the median scores.

An overall mean SIP score of 11.9 (s.d. 9.7; 95% C.I. 10.72 to 13.03), and median 9.5 has been obtained for pre-operative cataract patients, and the distribution had a wide spread of pre-operative scores about the mean (or median). This score represents a measure of the quality of life amongst these patients. Direct comparisons with other patient groups is difficult in that insufficient data are provided in published reports to make standardised comparisons (at least by age and sex). However taken at face value, this score for cataract patients is higher than that described for otherwise healthy adults [140], and for patients with angina and myocardial infarction [141], but lower than that describing patients with chronic conditions such as low back pain [142][143]; rheumatoid arthritis [144]; cancer [145] end-stage renal disease [146]; and chronic obstructive airways disease [147] [148].

The mean VR-SIP score was 1.8 (s.d. 2.7; 95% C.I. 1.5 to 2.2), and median 0.57, indicating little overall reported impact on patients' quality of life due to their vision. A floor effect was observed with a considerable proportion of patients (41%) not attributing any of their handicap to vision and thereby not being able to demonstrate any benefit from cataract surgery in this regard.

Examination of the category scores identified the category recreation and pastimes as having the highest scores in both SIP and VR-SIP, (in fact it was the only category that had a median above zero in VR-SIP). Work and home management were other high scoring categories in SIP. These, or similar categories (assessed by other instruments), have also been reported for patients with visual impairment in the community. [167] The other VR-SIP categories had very low median dysfunction scores suggesting that the presence of a cataract did not have a great impact on these categories of quality of life.

A significant change in the quality of life scores (in the direction of mean gain) was demonstrated after cataract surgery. These suggested an improvement in the overall quality of life and vision related quality of life after cataract surgery. The mean gains achieved at 4 months were maintained at one year after surgery in the group of patients that had surgery to their first eye only. The group of patients that had surgery to the second eye between 4 and 12 months of surgery to the first eye, demonstrated additional mean gains in quality of life at one year. Mean gains were also demonstrated in patients that did not achieve a good visual acuity outcome.

As already discussed in the previous chapter, although change in both the absolute SIP and VR-SIP scores was small, it was unlikely that the observed changes in quality of life scores were due to a placebo effect or due to a learning effect because the patient interview was conducted at sufficiently long intervals of 4 and 8 months of one another. However, as there was no control group of cataract patients that did not go on to have surgery for comparison, some influence from these effects cannot be completely overlooked.

Overall effect sizes were poor indicating that both SIP and VR-SIP had limited responsiveness to change, and that clinically important changes were likely to be small. Although change scores for SIP were better approximated to a normal distribution, the VR-SIP change scores remained highly skewed. Effect sizes were computed using the mean change in score post-operatively and the pre-operative standard deviation, as well as using the median change post-operatively and the pre-operative inter-quartile range. Effect sizes were consistently higher when computed from mean changes and pre-operative standard deviation and it is possible that in this situation, effect sizes computed in this manner are likely to provide overestimates. Consequently, further interpretation and discussion of effect size will be based on the computation of effect size from median change and pre-operative inter-quartile range as these provide a better estimate of effect size in this situation. Both computations were presented to illustrate this point and to provide consistency with methods employed in published literature.

It had been anticipated that the VR-SIP would more responsiveness to change than the SIP, but this was not observed. There are several possible explanations for the small effect sizes observed. A floor effect was present with the VR-SIP with 41% of patients having scores of zero before surgery i.e. reported that their quality of life was not affected by their vision. These patients could not demonstrate any gain after cataract surgery. This limited the responsiveness of the VR-SIP to change and also limited any improvement on the SIP in this regard, that it may have potentially been expected to provide.

In addition, examination of category scores suggested that many of the categories of quality of life measured were not affected in these cataract patients. Recreation and pastimes was identified as the category most affected before and after surgery. It was also the category where the both SIP and VR-SIP displayed greatest responsiveness to change, with moderate effect sizes for gain after surgery. Other categories of quality of life that were affected before surgery included work and home management (SIP). These were not identified as affecting quality of life affected by vision (VR-SIP). SIP demonstrated a large effect size after surgery for work, but not for home

management. A curious finding was greater dysfunction and handicap in the eating category post-operatively. This was only observed with SIP and no adequate explanation for this was found.

7. SUMMARY OF FINDINGS

The key findings relating to quality of life in cataract patients are :

- The SIP and VR-SIP displayed criterion validity for cataract patients and had limited responsiveness to change.

- Quality of life for cataract patients was not greatly affected by their vision Cataract had a greater effect on visual impairment (visual acuity in the surgery eye) and disability (visual functioning), than on handicap (quality of life).

- Cataract surgery improved quality of life

- Mean gains in quality of life after surgery to the first eye were maintained at one year

- Additional mean gains in quality of life were achieved after second eye surgery

- Mean gain in quality of life was achieved in patients with poor visual acuity outcome

Chapter 8.

THE CATARACT OUTCOME STUDY : RESULTS

RELATIONSHIPS BETWEEN VISUAL ACUITY, VISUAL FUNCTION AND QUALITY OF LIFE

1. INTRODUCTION

This chapter will present the findings relating to the relationships between the clinical and patient perceived measures of outcome examined in this thesis : visual acuity, visual function and quality of life. It was assumed that the sensory input from both eyes would influence visual function and quality of life. To allow for this, visual acuity was assessed in terms of the best corrected Snellen acuity in the surgery eye, the better eye and by VP% score (person visual acuity). Before relationships between the measures was could be examined, the visual acuity that was the most appropriate for this purpose had to be established. Although visual function and quality of life were significantly different after surgery, the *change* that was achieved (compared to pre-operative values) was of interest in assessing the inter-relationships between the clinical and patient perceived measures after surgery. Pre-operative findings are presented first, followed by the post-operative findings as follows :

- a description of the *relationship* between visual acuity and visual function and quality of life *before* surgery
- the *determinants* of visual function and quality of life *before* surgery
- a description of the *relationship* between change in visual function and visual acuity *after* surgery
- the *determinants* of change in visual function *after* surgery

2. CORRELATION OF VISUAL ACUITY WITH VISUAL FUNCTION AND QUALITY OF LIFE

As shown in Table 8.1, before surgery, the surgery eye visual acuity correlated poorly with the pre-operative visual function given by the VF-14 score, and the health-related and vision-related quality of life scores given by the SIP and VR-SIP scores, respectively. Correlations with better eye visual acuity and VP% scores were better and of a similar order.

Table 8.1. Correlation matrix : pre-operative measures of visual acuity with pre-operative visual function (VF-14) and quality of life (SIP and VR-SIP)

		VSEYADM	VBEYADM	VPADM
Surgery Eye Visual Acuity Pre-Op	**: VSEYADM**	--	--	--
Better Eye Visual Acuity Pre-Op	**: VBEYADM**	0.39	--	--
VP% Score Pre-Op	**: VPADM**	-0.58	-0.91	--
Pre-op Visual Function (VF-14) Score	**: VFADM**	-0.21	-0.48	0.45
Pre-op Sickness Impact Profile (SIP) score	**: SIPADM**	0.19	0.34	-0.33
Pre-op Vision-Related VR-SIP score	**: VR-SIPADM**	0.17	0.34	-0.34

All are Spearman Correlation Coefficients, p-value <0.01

Four months after surgery, all the measures of visual acuity had similar correlation coefficients with the visual function(VF-14) and health (SIP) and vision-related (VR-SIP) quality of life scores. Table 8.2

Table 8.2 **Correlation matrix : measures of visual acuity with visual function (VF-14) and quality of life (SIP and VR-SIP) at 4 MONTHS after surgery**

		VSEY4M	VBEY4M	VP4M
Surgery Eye Visual Acuity 4 Months	**: VSEY4M**	–	–	–
Better Eye Visual Acuity 4 Months	**: VBEY4M**	0.89	–	–
VP% Score 4 Months	**: VP4M**	-0.67	-0.73	–
Visual Function (VF-14) score 4 months	**: VF14-4M**	-0.31	-0.34	0.33
Sickness Impact Profile (SIP) score 4 months	**: SIP4M**	0.25	0.25	-0.24
Vision-Related VR-SIP score 4 months	**: VR-SIP4M**	0.23	0.23	-0.23

All are Spearman Correlation Coefficients, p-value <0.01

At twelve months after surgery, although correlations with the measures of visual acuity were similar for visual function (VF-14), and vision-related quality of life (VR-SIP), they were higher for better eye visual acuity and VP% score. Correlations with health-related quality of life were better with surgery eye acuity and better eye acuity than with VP% score. Table 8.3.

Table 8.3 **Correlation matrix : measures of visual acuity with visual function (VF-14) and quality of life (SIP and VR-SIP) at 12 MONTHS after surgery**

		VSEY12M	VBEY12M	VP12M
Surgery Eye Visual Acuity 12 Months	**: VSEY12M**	–	–	–
Better Eye Visual Acuity 12 Months	**: VBEY12M**	0.82	–	–
VP% Score 12 Months	**: VP12M**	-0.63	-0.66	–
Visual Function (VF-14) score 12 months	**: VF14-12M**	-0.31	-0.38	0.39
Sickness Impact Profile (SIP) score 12 month	**: SIP12M**	0.27	0.24	-0.15
Vision-Related VR-SIP score 12 months	**: VR-SIP12M**	0.29	0.34	-0.33

All are Spearman Correlation Coefficients, p-value <0.01

3. PRE-OPERATIVE RELATIONSHIPS

In addition to the correlations with visual acuity presented above, as seen in Table 8.4, VF-14 scores before surgery correlated strongly with VR-SIP scores measuring quality of life affected by vision (correlation coefficient = -0.71). Both VF-14 and VR-SIP correlated moderately well with global measures of vision. SIP scores measuring overall quality of life correlated less well with visual function (correlation coefficient = -0.37), and poorly with global measures of vision.

Table 8.4 Pre-operative Correlation Matrix : SPEARMAN Correlation Coefficients

	VFSD	BV	V-Person	SV	"Trouble"	"Satisfaction"	SIP	VR-SIP
VF score on admission (VFSD)	---							
Vision in Better Eye on admission (BV)	0.4763	---						
V-Person Score vision for person on admission	0.4537	-0.9095	---					
Vision in Surgery Eye on admission (SV)	-0.2065	0.3949	-0.5773	---				
Amount of "trouble" with vision	-0.5553	0.3773	-0.3724	0.1919 *	---			
Amount of "dissatisfaction" with vision	-0.488	0.3252	-0.3232	0.1884 *	0.5445	---		
SIP Score on Admission (SIP)	-0.3713	0.3359	-0.3349	0.1818 *	0.2200	0.2155	---	
Vision-Related SIP Score (VR-SIP) on admission	-0.7054	0.3391	-0.3436	0.1696 *	0.4833	0.3978	0.4037	---

* Spearman Correlation Coefficients with a p-value <=0.007
All other Spearman Correlation Coefficients presented have a p-value <0.0001

3.1 Visual Function Before Surgery

3.1.1 Relationship (unadjusted) between Pre-operative VF-14 Score and Continuous Pre-operative Variables

These are summarised in Table 8.5.

Table 8.5. Relationship (unadjusted) between : Pre-Operative VF-14 Score and Continuous Pre-Operative Variables. N = 337 cases

Variable	Correlation Coefficient (Spearman's)	p-value	Regression Coefficient Coefficient	beta	p-value	R-square
Pre-Operative Better Eye Visual Acuity	0.4763	<0.0001	7.57	0.55	<0.0001	0.3
Age (on admission)	-0.0109	0.842	0.002	0.0007	0.99	<0.001

Scatterplots were plotted and the diagnostics for the regression coefficients were satisfactory.

The Spearman correlation coefficient was 0.48. The regression coefficient was 7.6 (p-value <0.0001), suggesting that the VF-14 score improves as visual acuity in the better eye improves. For every one unit change in better eye vision (approximates to one line of Snellen acuity), then on average there will be a change of 7.6 units in the VF-14 score. 30% of the variability in VF-14 scores was explained by visual acuity in the better eye (R-squared = 0.3). The diagnostics for the validity of the regression model were satisfactory and confirmed a significant linear relationship between the visual function and visual acuity in the better eye.

No significant relationship was observed between age and pre-operative VF-14 score.

3.1.2 Relationship (unadjusted) between Pre-operative VF-14 Score and Categorical Pre-operative Variables

The mean VF-14 scores were examined by : visual acuity group for better eye on admission, global self assessments of vision, age group , sex and presence of ocular comorbidity (Table 8.6). Overall there was a wide variation in scores about the mean score for all the sub-groups of the variables considered, as seen by the standard deviations of the mean scores.

As visual acuity decreased from good acuity to blindness, then mean VF-14 score fell also. The mean scores for severe visual impairment and blindness are not significantly different from each other. There are smaller numbers of patients in these two groups and the confidence intervals for these means are wide. However, as seen for any level of visual acuity, there is a wide spread of scores about the mean score.

The global assessments of vision showed a similar pattern - as the amount of "trouble with vision" reported increased, or the amount of "dissatisfaction with vision" increased, the group mean VF-14 scores fell.

No significant differences were observed in the mean VF-14 scores by age group, sex or the presence or absence of ocular comorbidity.

Table 8.6 Relationship (unadjusted) of Pre-Operative VF-14 Score and Pre-Operative Categorical Variables

	n	Mean VF-14 score	(s.d.)	95% C.I. for Mean
Better Eye				
Visual Acuity *				
6/6 to 6/12	181	76.2	(16.6)	73.8 to 78.6
6/18 to 6/24	92	62.2	(23.4)	57.4 to 67.1
6/36 to 6/60	20	42.9	(24.0)	31.7 to 54.1
blind	7	28.9	(20.3)	10.1 to 47.7
Reported "Trouble" with Vision *				
none	8	85.8	(15.6)	72.8 to 98.9
little	46	86.3	(13.9)	82.2 to 90.5
moderate	142	73.6	(16.9)	70.7 to 76.4
great deal	104	52.6	(22.8)	48.2 to 57.1
Reported "Satisfaction" with Vision *				
satisfied	26	89.7	(11.7)	84.8 to 94.5
dissatisfied	193	71.8	(20.2)	68.9 to 74.7
very dissatisfied	81	54.0	(22.0)	49.2 to 58.9
Ocular Comorbidity #				
absent	204	70.2	(21.7)	67.2 to 73.2
present	96	65.1	(65.1)	60.3 to 69.9
Age (years) #				
50 to 64	33	65.6	(22.6)	57.6 to 73.6
65 to 74	97	68.4	(22.3)	63.9 to 72.9
75 and over	170	69.3	(22.6)	65.9 to 72.2
Sex #				
males	113	71.8	(23.7)	67.6 to 76.2
females	187	66.7	(21.6)	63.6 to 69.8

* Kruskal-Wallis p-value < 0.0001
\# one-way anova p-value > 0.05

3.1.3 The Determinants of Pre-operative VF-14 Score

Since the crude analysis suggested that visual acuity could "explain" only 30% of the variability in the VF-14 scores observed, other factors were most likely to be contributing to the VF-14 score itself, and to the variation in scores for any particular sub-group. The influence of other independent factors on VF-14 score was considered in a multiple regression model. The variables in the model were :

Dependent variable - pre-operative VF-14 score (VFSD)

Independent variables -

Age : 50-64 years *(referent group)*
65-74 years
75 years and over

Better eye visual acuity : 6/6 to 6/12 - good
6/18 to 6/24 - moderate impairment
6/36 or worse - severe impairment *(referent group)*

Sex : male = 0 *(referent group)*
female = 1

Ocular comorbidity : absent = 0 *(referent group)*
present = 1

Comorbidity "bothersome-ness" score (continuous variable)

Cataract Symptom score (continuous variable)

The diagnostics for the validity of this model were satisfactory [Appendix C2] and the findings are summarised in Table 8.7.

Table 8.7 Determinants of Pre-Operative Visual Function (Pre-Operative VF-14 Score)

Multiple Regression Model

Dependent Variable : Pre-Operative VF-14 Score (VFSD)

Model Characteristics :

Multiple R = 0.61
R-square = 0.38
Adjusted R-square = 0.36
Standard Error = 17.99

F = 22.1
Significance of F <0.0001

Variables in Model	Coefficient	[95% C.I.]	beta	p-value
Visual Acuity in Better Eye on admission:				
Severe Impairment: <=6/36	referent			
Visual Impairment: 6/18 to 6/24	22.13	[14.3 to 29.9]	0.75	<0.0001
Good visual acuity: 6/6 to 6/12	34.55	[27.0 to 42.1]	0.45	<0.0001
Ocular Comorbidity				
present	-1.061	[-5.5 to 3.4]	-0.02	0.6
Cataract Symptom Score	-0.25	[-0.3 to -0.2]	-0.3	<0.0001
Comorbidity "bothersome" score	-0.53	[-0.8 to -0.2]	-0.2	<0.001
Age :				
50 to 64 years	referent			
65 to 74 years	4.16	[-3.1 to 11.4]	0.1	0.26
75 years and over	7.70	[0.7 to 14.7]	0.2	0.03
Sex :				
female	-2.34	[-6.7 to 2.0]	-0.05	0.29

This model explained 38% of the variability of the VF scores (R-square = 0.38), having adjusted for all the other variables in the model. It demonstrates the presence of a linear relationship between VF-14 score and the other independent variables (F=22.1, significance of F <0.00005).

The variables with significant partial regression coefficients identified by this model are better eye visual acuity, comorbidity "bothersome" score, cataract symptom score and age. The coefficient for better eye visual acuity was positive, indicating that, having adjusted for the other variables in the model, as visual acuity improves the VF-14 score rises, with a greater average change of visual function score for unit of visual acuity change in the group with good pre-operative better eye visual acuity. Comorbidity and cataract symptoms have negative coefficients indicating that as these scores rise (worsening of comorbidity or cataract symptoms) visual function deteriorates.

The positive regression coefficients for age suggest that visual function score rises on average with age, having adjusted for all the other variables in the model. As seen above, the crude relationship between VF-14 scores and age did not indicate this. In case the effect seen in the model was due to the fact that there were small numbers of people in the referent group (youngest age group, n=33) , the model was then fitted, first with age considered in just two groups of under 75 years and 75 years or over, and then it was next fitted with age as a continuous variable. Neither of these changed the relationship between age and VF-14 score having adjusted for all the other variables in the model.

Although ocular comorbidity and sex did not demonstrate any significant relationships with baseline VF-14 score in the regression model, they are both significantly correlated with better eye visual acuity (Spearman correlation coefficients -0.1433, p-value = 0.012 and -0.1921, p-value = 0.001, respectively). It is possible that they may be operating through their relationship with visual acuity and do not have any unique contribution to make to the model.

An analysis of variance with better eye visual acuity as the covariate, VF-14 score as dependent variable, and age group, sex and ocular comorbidity as factors, did not demonstrate any significant effects either as main effects or as interactions between the factors. The relationship between better eye visual acuity and VF-14 score was similar when controlling for age, sex and ocular comorbidity.

The regression model was then fitted with age as the dependent variable and all the others as independent variables, to explore the factors associated with age, particularly acuity which may be influencing the effect observed on VF-14 scores. The findings are summarised in Table 7.8 (details are provided in Appendix C2). As the partial regression coefficients indicate, after adjustment for the other variables in the model, visual acuity falls with increasing age and visual function improves with increasing age. Cataract symptom score falls with rising age, whilst general comorbidity "bothersome" score rises on average with age.

The model was then fitted excluding cataract symptom score, in case the effect of age on visual function was working through this, but the age and visual function relationship persisted. Only the full model is presented in Table 8.8 .

Table 8.8 Pre-Operative Factors Associated with AGE on admission for cataract surgery.

Multiple Regression Model

Dependent Variable : AGE (continuous)

Model Characteristics :

Multiple R = 0.41
R-square = 0.16
Adjusted R-square = 0.14
Standard Error = 7.64

F = 8.24
Significance of F <0.0001

Variables in Model	Coefficient	[95% C.I.]	beta	p-value
Visual Acuity in Better Eye on admission:				
Severe Impairment: <=6/36	referent			
Visual Impairment: 6/18 to-6/24	-3.55	[-7.0 to -0.07]	-0.2	0.04
Good visual acuity: 6/6 to 6/12	-7.60	[-11.2 to -4.0]	-0.45	< 0.0001
Ocular Comorbidity :				
present	1.81	[-0.1 to 3.7]	0.1	0.06
Cataract Symptom Score :	-0.05	[-0.1 to -0.01]	-0.15	0.007
Comorbidity "bothersome" score :	0.14	[0.01 to 0.3]	0.12	0.03
Pre-Operative VF-14 score (VFSD) :	0.05	[0.01 to 0.2]	0.15	0.02
Sex :				
female	2.4	[0.6 to 4.2]	0.14	0.01

3.2 Quality of Life Before Surgery

3.2.1 Relationship (unadjusted) Between Health-Related Quality of Life (SIP) and other Pre-operative Continuous Variables

These are summarised in Table 8.9.

Table 8.9. Relationship (unadjusted) between : Pre-Operative SIP Score (SIP) and other Pre-operative Continuous Variables. N= 273 cases

Variable	Regression Coefficient	[95% C.I]	beta	p-value	R-square
Age (on admission)	0.31	[0.18 to 0.45]	0.27	< 0.0001	0.07
Comorbidity "Bothersome" Score	0.82	[0.68 to 0.96]	0.60	< 0.0001	0.36
Pre-Operative Better Eye Visual Acuity	-1.65	[-2.33 to -0.98]	-0.29	< 0.0001	0.09
Pre-Operative Visual Function Score	-0.17	[-0.22 to -0.12]	-0.39	< 0.0001	0.15

Scatterplots, correlation coefficients, and diagnostics for regression coefficients were performed and were satisfactory.

As the regression coefficient (0.31) indicates, SIP scores rise with increasing age. Although a significant linear relationship was demonstrated, the impact of age on overall SIP score is small as it only explains 7% of the variability of the pre-operative scores (R-square = 0.07).

The coefficients indicate that SIP scores rise with increasing "bothersome-ness" from other comorbidities (regression coefficient 0.82). A significant linear relationship was demonstrated, with 36% of the variability of the pre-operative SIP score (R-square = 0.36) being explained by the comorbidity "bothersome" score.

The negative regression coefficient (-1.65) indicates that SIP scores rise with decreasing visual acuity in the better eye. However better eye visual acuity could only explain 9% of the variability of the SIP score (R-square =0.09).

The negative coefficients (correlation -0.37 and regression -0.17), indicate that SIP scores rise as visual functioning decreases. About 15% of the variability of the pre-operative SIP scores could be explained by the visual function score (R-square = 0.15).

3.2.2 Relationship (unadjusted) Between Vision-Related Quality of Life (VR-SIP) and other Pre-operative Continuous Variables

These are summarised in Table 8.10. There was a strong correlation with VR-SIP (Spearman correlation coefficient -0.71). Although a linear relationship was demonstrated, with 41% of the variability in pre-operative VR-SIP scores being explained by the visual function score (R-square = 0.41), the unadjusted regression coefficient was -0.095 suggesting very little change in average VR-SIP score with unit increase in visual function score.

Similarly, for VR-SIP scores, as indicated by the negative regression coefficient (-0.78), VR-SIP scores rose with poorer visual acuity in the better eye. 14% of the variability of the pre-operative VR-SIP scores being explained by better eye visual acuity.

For comorbidity and age regression coefficients were not valid as the diagnostics for the model were highly unsatisfactory and a linear relationship could not be demonstrated.

Table 8.10. Relationship (unadjusted) between : Pre-Operative VR-SIP Score (VR-SIP) and other Pre-operative Continuous Variables. N = 273 cases

Variable	Regression Coefficient	[95% C.I.]	beta	p-value	R-square
Pre-Operative Visual Function Score	-0.095	[-0.11 to -0.08]	-0.64	< 0.0001	0.41
Pre-Operative Better Eye Visual Acuity	-0.78	[-1.02 to -0.54]	-0.38	< 0.0001	0.14
Comorbidity "Bothersome" Score	0.05	[-0.01 to 0.11]	0.09	0.12	0.01

Scatterplots, correlation coefficients and diagnostics for regression coefficients were performed and were satisfactory.

3.2.3 Relationship (unadjusted) of Pre-operative SIP Score and Categorical Pre-operative Variables

The mean SIP scores were then examined by : age group, sex, comparative assessments of health, visual acuity group for better eye on admission, global self assessments of vision, and presence of ocular comorbidity, and are shown in Table 8.11. Overall there was a wide variation in scores about the mean score for any of the sub-groups of the variables considered, as seen by the standard deviations of the mean scores.

Both the mean and median SIP scores were higher with increasing age. The oldest age group 75 years and over had significantly higher scores than the 65 to 74 year age group. Although no significant difference was observed between the 50 to 64 year age group and the other age groups, this group had fewer numbers and wider confidence intervals, which must be considered in its interpretation. Pre-operative SIP scores were higher amongst females, as comparative assessments of health were towards poorer health, with poorer visual acuity in the better eye, and with greater reporting of trouble with vision and dissatisfaction with vision.

Table 8.11.
Relationship (unadjusted) between Pre-operative SIP and Pre-operative Categorical Variables

	n	Mean SIP Score	s.d.	95% C.I. for Mean Score	Median	Inter-quartile Range
Age (years)						
50 to 64	30	9.3	10.1	5.5 to 13.1	6.2	29.7
65 to 74	83	10.1	8.8	8.2 to 12.0	7.5	23.3
75 and over	160	13.3*	9.8	11.8 to 14.8	11.0	28.1
Sex ##						
males	109	10.0	9.0	8.3 to 11.7	8.1	23.6
females	164	13.1	9.9	11.6 to 14.7	10.7	27.3
Comparative Assessment of Health :						
C1. "Is your health ..?" #						
Excellent	30	7.0	6.6	4.6 to 9.5	5.4	21.1
Very good	87	8.0	6.4	6.7 to 9.4	6.7	13.3
Good	78	11.3	7.8	9.5 to 13.0	8.9	20.0
Fair	53	15.8	10.2	12.9 to 18.6	12.8	25.6
Poor	24	24.3	12.0		25.0	27.1
C2. "Compared to others ?"#						
Much better	74	8.1	6.9	6.8 to 10.0	7.1	20.1
Better	108	10.4	8.7	8.8 to 12.0	8.6	20.5
About the same	67	15.0	10.4	12.4 to 17.5	11.2	27.0
Worse	19	20.2	10.6	15.1 to 25.3	21.8	31.4
Much worse	2	33.8	0.5	-	33.8	0.7
Best Eye Vision #						
6/6 to 6/12	153	9.7	8.3	8.4 to 11.0	7.5	22.0
6/18 to 6/24	72	13.2	9.4	11.0 to 15.5	11.1	26.7
6/36 to 6/60	19	19.7	12.8	13.5 to 25.8	17.2	37.7
blind	6	15.5	4.5	10.8 to 20.2	15.0	10.4
Reported "Trouble" with Vision						
none	9	11.8	9.8	4.2 to 19.3	5.5	20.8
little	42	9.9	8.6	7.2 to 12.6	8.2	22.3
moderate	131	10.4	9.2	8.8 to 12.0	8.4	26.4
great deal	91	14.9 *	10.2	12.8 to 17.0	11.3	26.6
Reported "Satisfaction" with Vision ##						
satisfied	27	10.3	11.2	5.9 to 14.8	5.5	27.2
dissatisfied	175	10.7	8.7	9.4 to 11.9	8.9	28.6
very dissatisfied	69	15.4	10.5	12.8 to 17.9	12.5	27.1
Ocular Comorbidity ##						
absent	173	10.8	8.6	9.5 to 12.0	8.9	21.5
present	81	13.8	10.7	11.4 to 16.2	11.0	28.7

\# - Kruskal-Wallis Test $p < 0.0005$

\## - Kruskal-Wallis Test $p < 0.05$

Unless indicated otherwise, all other group comparisons were made by a one-way analysis of variance with adjustment for multiple comparisons being made by the Bonferroni test. $p<0.05$

3.2.4 Relationship (unadjusted) of Pre-operative VR-SIP Score and Categorical Pre-operative Variables

The mean VR-SIP scores were then examined as above with similar sub-groups of pre-operative variables and are presented in Table 8.12. Overall there was a wide variation in scores about the mean score for any of the sub-groups of the variables considered, as seen by the standard deviations of the mean scores.

No significant differences were observed in the mean or median VR-SIP scores by age group, or by the presence or absence of ocular comorbidity. Both the mean and median VR-SIP scores rose with poorer visual acuity in the better eye and with greater trouble and dissatisfaction with vision.

Table 8.12.
Relationship (unadjusted) : Pre-Operative VR-SIP Scores and Pre-operative Categorical Variables

	n	Mean VR-SIP Scor	s.d.	95% C.I. for Mean Score	Median	Inter-quartile Range
Age (years) *						
50 to 64	30	3.0	4.7	1.3 to 4.8	0.2	5.1
65 to 74	83	2.1	3.6	1.3 to 2.9	0.9	2.6
75 and over	160	1.5	2.8	1.1 to 1.9	0.5	1.6
Sex ##						
males	109	1.9	4.0		0.0	1.7
females	164	1.9	2.8		0.8	2.6
Best Eye Vision #						
6/6 to 6/12	153	1.1	2.0	0.8 to 1.5	0.4	1.3
6/18 to 6/24	72	2.4	4.3	1.4 to 3.4	0.7	2.7
6/36 to 6/60	19	4.8	5.5	2.2 to 7.5	3.3	6.1
blind	6	6.9	2.5	4.3 to 9.6	7.5	4.5
Reported "Trouble" with Vision - A1 #						
none	9	1.5	2.3	-0.3 to 3.2	0.0	2.8
little	42	0.3	0.5	0.1 to 0.4	0.0	0.4
moderate	131	1.1	2.4	0.7 to 1.5	0.4	1.3
great deal	91	3.7	4.4	2.8 to 4.6	2.4	4.3
Reported "Satisfaction" with Vision - A2 #						
satisfied	27	0.3	0.9	-0.1 to 0.7	0.0	0.0
dissatisfied	175	1.4	2.6	1.0 to 1.8	0.5	1.6
very dissatisfied	69	3.6	4.7	2.5 to 4.7	2.0	3.4
Ocular Comorbidity *						
absent	173	1.7	3.3	1.2 to 2.2	0.6	1.9
present	81	2.3	3.6	1.5 to 3.0	0.8	2.9

\# - Kruskal-Wallis Test $p < 0.0005$
\## - Kruskal-Wallis Test $p < 0.05$
* - No significnat differences between groups demonstrated by both parametric and non-parametric tests

Unless indicated otherwise, all other group comparisons were made by a one-way analysis of variance with adjustment f multiple comparisons being made by the Bonferroni test $p < 0.05$

3.2.5 The Determinants of Pre-operative Quality of Life

Given the crude relationships described above, multiple regression models were used to identify the independent factors that were the determinants of pre-operative SIP and VR-SIP scores, having adjusted for the effect of other important variables.

a. Determinants of Pre-Operative SIP Score

Sex, ocular comorbidity and better eye visual acuity were included in the initial model building process, but were found to be non-significant factors not contributing to the model. In the interest of simplicity, these variables were excluded from the final model, so that the latter may be optimally efficient. The final model included age, comorbidity "bothersome" score and pre-operative visual function score. The diagnostics for the validity of the final model were satisfactory [Appendix C3] and the findings are summarised in Table 8.13.

Table 8.13 Determinants of Pre-Operative SIP Score.

Multiple Regression Model

N = 249
Dependent Variable : Pre-Operative SIP Score (TOTAL)

Model Characteristics :

Multiple R = 0.69
R-square = 0.48
Adjusted R-square = 0.47
Standard Error = 6.79

Variables in Model	Coefficient	[95% C.I]	beta	p-value
Comorbidity "bothersome-ness"	0.69	[0.56 to 0.82]	0.51	< 0.0001
Pre-Operative Visual Function Score	-0.12	[-0.16 to -0.08]	-0.29	< 0.0001
Age	0.24	[0.13 to 0.34]	0.21	< 0.0001

This model explained 48% of the variability of the pre-operative SIP scores. Having adjusted for the effects of the other variables in the model, comorbidity "bothersome" score was the single most important determinant of pre-operative SIP score in this model (having the highest standardised beta 0.51). The effects of the other variables on the standardised beta for comorbidity "bothersome" score was minimal, the unadjusted standardised beta being 0.6 (as seen in Table 8.9).

Age and pre-operative visual function score were significant independent determinants of pre-operative SIP score.

b. Determinants of Pre-Operative VR-SIP Score

Sex and ocular comorbidity were not included in the final model because they did not contribute significantly in the initial models. The final model included visual function score, better eye visual acuity, and age on admission. The diagnostics for the final model were satisfactory and are provided in Appendix C4. The findings are summarised in Table 8.14.

This model explained 41% of the variability of pre-op VR-SIP scores. Pre-operative visual function (VF-14 score) was the most important determinant of VR-SIP score, (standardised beta -0.59), having adjusted for the other variables in the model. Adjustment for the effects of the other variables in the model had little impact on the estimates of the unadjusted regression coefficient and standardised beta for visual function score (as seen in Table 8.10).

Age and better eye visual acuity on admission were not significant, once the effect of visual function score had been controlled for. Age was included in this model to adjust for its effect on better eye acuity and visual function score. Better eye acuity is significantly correlated with visual function score (correlation coefficient 0.4763) and

presumably does not have any significant unique contribution to make to the model above that operating through visual function score.

Table 8.14. Determinants of Pre-Operative VR-SIP Score.

Multiple Regression Model

N = 250
Dependent Variable : Pre-Operative VR-SIP Score (VTOTAL)

Model Characteristics :

Multiple R = 0.66
R-square = 0.44
Adjusted R-square = 0.43
Standard Error = 2.58

Variables in Model	Coefficient	[95% C.I.]	beta	p-value
Pre-Operative Visual Function Score	0.09	[-0.11 to -0.07]	-0.59	< 0.0001
Pre-Operative Better Eye Visual Acuity	-0.16	[-0.41 to 0.09]	-0.08	0.22
Age (on admission)	-0.04	[-0.09 to 0.001]	-0.10	0.06

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4. POST-OPERATIVE RELATIONSHIPS

Since change in measures of quality of life were small, that a significant proportion of patients reported that their quality of life was not affected by their vision (41%), and the effect sizes for SIP and VR-SIP were poor, further analysis of the relationships between visual acuity and the change in quality of life, and the determinants of change in quality of life were not pursued.

Post-operative relationships between visual acuity and visual function at 4 and 12 months after surgery were examined and are now presented.

4.1 Relationship (unadjusted) of CHANGE in VF-14 Score After Surgery and Continuous Variables

These are summarised in Table 8.15 and Table 8.16 for change at 4 and 12 months respectively.

Pre-Operative VF-14 Score

Significant linear relationships was demonstrated between pre-operative visual functioning and the change achieved after surgery. The negative regression coefficients after surgery suggest that on average poorer pre-operative VF-14 score had more change in visual function at 4 and 12 months after surgery. 47% of the variability in change in visual function scores at 4 months was being explained by the pre-operative visual function scores (R-squared = 0.47), with 60% of the variability of change in VF-14 scores at 12 months after surgery being explained by the pre-operative scores (R-squared = 0.6).

Pre-Operative Visual Acuity in Better Eye

The negative regression coefficients suggest that patients with poorer pre-operative visual acuity in the better eye on average, achieved more change (gain) in visual function than patients with better pre-operative acuity in the better eye. Although significant linear relationships were demonstrated, pre-operative better eye visual acuity could only explain about 8% of the variability of the change in VF-14 scores at 4 months and 9% at 12 months after surgery. (Table 8.15 and 8.16)

Change in Visual Acuity in Better Eye at 4 Months after Surgery

The positive regression coefficients indicate that as more change in better eye visual acuity was achieved post-operatively, then more change (gain) in visual function was achieved. Linear relationships were demonstrated. The change in better eye acuity explained 11% of the variability of the change in VF-14 scores at 4 months (R-square = 0.11), and 24% of the variability at 12 months (R-square = 0.24).

Table 8.15 Relationship (unadjusted) between : Change in VF-14 Score 4 MONTHS After Surgery and Continuous Variables. n = 316 cases

Variable	Regression Coefficient [95% C.I]	beta	p-value	R-square
Pre-Operative VF-14 Score (VFSD)	-0.64 [-0.72 to -0.57]	-0.69	< 0.0001	0.47
Pre-Operative Better Eye Visual Acuity (BVHI)	-3.6 [-5.01 to -2.18]	-0.28	< 0.0001	0.08
Change in Better Eye Visual Acuity 4 Months after surgery (BVCH4M)	4.86 [3.20 to 6.53]	0.34	< 0.0001	0.11

Scatterplots, correlation coefficients (Pearson and Spearman) and diagnostics for regression coefficients were performed and were satisfactory.

Table 8.16 Relationship (unadjusted) between Change in VF-14 Score 12 MONTHS After Surgery and Continuous Variables. n = 278 cases

Variable	Regression Coefficient [95% C.I]	beta	p-value	R-square
Pre-Operative VF-14 Score : (VFSD)	-0.73 [-0.79 to -0.66]	-0.78	< 0.000	0.60
Pre-Operative Better Eye Visual Acuity (BVHI) :	-3.93 [-5.44 to -2.42]	-0.3	< 0.000	0.09
Change in Better Eye Visual Acuity 12 months after surgery(BVCH12M) :	7.09 [5.38 to 8.80]	0.49	< 0.000	0.24

Scatterplots, correlation coefficients (Pearson and Spearman) and diagnostics for regression coefficients were performed and were satisfactory.

4.2 Relationship (unadjusted) between CHANGE in VF-14 Score After Surgery and Categorical Variables

These are summarised in Table 8.17 and 8.18 for change at 4 and 12 months respectively.

There was a wide spread of scores about the mean change for all sub-groups considered, as indicated by the standard deviations of the sub-group means. The mean change in visual function after surgery at both 4 and 12 months was higher amongst patients with poorer pre-operative visual acuity in the better eye. No significant differences were observed by age group, sex, the presence or absence of ocular comorbidity, and at 4 months, by visual acuity outcome. Second eye surgery was associated with a greater mean change in visual function at 12 months.

Table 8.17 **Change in VF-14 Score at 4 Months Post-Operatively by Sub-Group of Categorical Variables**

	n	Mean Change VF-14 score (s.d.)	95% C.I. for Mean	Median	Inter-quartile range
Better Eye Visual Acuity on Admission #					
6/6 to 6/12	178	15.37 (15.93)	13.02 to 17.7	12.50	22.76
6/18 to 6/24	89	26.10 (23.61)	21.13 to 31.1	24.32	34.46
6/36 to 6/60	21	32.40 (29.14)	19.14 to 45.7	23.86	41.82
blind	7	27.95 (36.31)	-5.64 to 61.5	20.45	59.44
Ocular Comorbidity *					
absent	207	19.85 (20.17)	17.01 to 22.7	15.91	25.41
present	93	21.43 (21.41)	16.03 to 24.8	15.91	30.00
Age (yrs) *					
50 to 64	34	25.42 (19.34)	18.67 to 32.2	22.82	30.44
65 to 74	98	21.23 (18.63)	17.49 to 24.9	17.84	25.00
75 and over	184	18.08 (22.18)	14.85 to 21.3	13.55	26.42
Sex *					
males	122	17.23 (19.02)	13.82 to 20.6	12.50	17.50
females	194	21.49 (21.91)	18.39 to 24.5	20.29	30.45
Visual Acuity Outcome *					
good (6/12 or better)	228	20.6 (21.1)	17.9 to 23.4		
poor (less than 6/12)	40	16.1 (20.2)	9.7 to 22.6		

\# Kruskal-Wallis p-value = 0.0008

* No significant differences demonstrated p-value >0.05

Table 8.18 **Relationship (unadjusted) between Change in VF-14 Score at 12 Months after surgery and other Categorical Variables**

Variable	n	Mean Change in VF-14 Score (s.d.)	95% C.I for Mean Change	Median Change in VF-14 Score	Inter-quartile Range
Better Eye Visual Acuity on Admission #					
6/6 to 6/12	161	17.9 (16.7)	[15.4 to 20.6]	15.7	23.7
6/18 to 6/24	78	29.4 (23.9)	[23.9 to 34.8]	26.8	32.9
6/36 to 6/60	16	37.2 (26.3)	[23.2 to 51.2]	30.9	37.1
blind	6	32.9 (29.9)	[1.6 to 64.3]	29.1	28.9
Ocular Comorbidity *					
absent	184	24.0 (20.6)	[21.0 to 27.0]	20.8	28.3
present	81	20.1 (21.7)	[15.3 to 24.9]	16.7	23.1
Second Eye Surgery ##					
no	192	18.9 (19.6)	[16.2 to 21.8]	15.9	25.5
yes	86	30.9 (20.9)	[26.5 to 35.5]	28.0	29.6
Age (yrs) *					
50 to 64	28	29.1 (18.6)	[21.9 to 36.4]	26.9	24.9
65 to 74	86	24.3 (20.9)	[19.8 to 28.7]	21.8	25.9
75 and over	164	20.8 (20.9)	[17.5 to 23.9]	16.1	29.4
Sex *					
males	112	20.7 (19.1)	[17.01 to 24.1]	14.6	20.8
females	166	24.1 (21.8)	[20.78 to 27.5]	24.0	30.2

\# Kruskal-Wallis p-value = 0.0003

\#\# One way analysis of variance p-value < 0.05

* No significant differences demonstrated p-value > 0.05

4.3 The Determinants of CHANGE in VF-14 Score After Surgery

For all the models described in this section, the tests for homogeneity of variance (Cochran's test and Bartlett-Box test), and the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid for all the models described. These details are presented in full in Appendix D (D1, D2, D3 and D4).

Sex was included in the initial model building process, but was found to be a non-significant factor that did not contribute to the models. In the interest of simplicity, the SEX variable was excluded from the final ANOVA models, so that the latter may be optimally parsimonious.

4.3.1 Relationship between Change in Visual Function Score and Visual Acuity

The models below describe the pragmatic linear relationship between change in visual function after cataract surgery and visual acuity, first using pre-operative better eye visual acuity and second, the change in better eye visual acuity post-operatively. The relationships at 4 months and 12 months were considered in separate models.

a. Using pre-operative better eye visual acuity

The models were fitted with change in visual function (at 4 months and 12 months) as the dependent variable, with pre-operative better eye visual acuity and age as covariates. Ocular comorbidity was a factor in both the 4 and 12 month models, with second eye surgery as an additional factor in the 12 month model. The findings at 4 months are summarised in Table 7.19 and in Table 7.20 for those at 12 months.

At 4 months the overall model explained 10.3% of the variability of the change in visual function (R-square = 0.103; model adjusted R-square = 0.093). At 12 months after surgery the overall model explained 19.7% of the variability of the change in visual function (R-square = 0.197; model adjusted R-square= 0.181).

The findings suggested that after adjustment for the other variables in the model, ocular comorbidity was not a significant factor influencing change in visual function after surgery. At 12 months however, second eye surgery performed by 12 months of the first cataract extraction was a significant factor after adjustment for the effects of the other variables in the model. The combined adjusted mean change in visual function score at 12 months was significantly and substantially higher in patients who had second eye surgery compared to those who had not (29.28 v. 19.88). There was no significant interaction at 12 months whereby the association of second eye surgery with change in visual function score might depend upon whether or not ocular comorbidity was present (the interaction p-value was 0.56)

Pre-operative better eye visual acuity was a significant covariate associated with change in visual function after surgery. The data suggested that, after controlling for age, patients with poorer pre-operative better eye visual acuity tend on average to gain more visual function after surgery (regression coefficient = -4.25 at 4 months and -4.61 at 12 months).

Age was also a significant covariate associated with change in visual function after surgery. The findings suggested that after controlling for the other variables in the model, change in visual function decreased with increasing age (regression coefficient = -0.44 at 4 months and -0.51 at 12 months).

Table 8.19 **Change in Visual Function 4 MONTHS after surgery and Pre-operative Better Eye Visual Acuity**

ANOVA : 272 cases with complete data

Variables in Model	Coefficient [95% C.I]	beta	p-value	Adjusted Mean VFCH12M
FACTORS				
Ocular comorbidity (OH):	0.36 [-2.31 to 3.02]		0.792	OH absent 20.38 present 19.67
COVARIATES				**Average R-squared ***
Pre-Operative Better Eye Visual Acuity :	-4.25 [-5.81 to -2.69]	-0.33	< 0.001	0.74
Age on Admission :	-0.44 [-0.74 to -0.13]	-0.17	0.006	0.05

* Squared correlation between covariates and predicted VFCH4M

R-Square = 0.103
Model Adjusted R-squared = 0.093

The tests for homogeneity of variance gave p-values of 0.763 and 0.779. These, together with the analysis of residuals suggest that no serious violations occurred and that the ANOVA analysis was valid (Appendix D3

Table 8.20 **Change in Visual Function 12 MONTHS after surgery and Pre-operative Better Eye Visual Acuity**

ANOVA : 261 cases with complete data

Variables in Model	Coefficient [95%C.I]	beta	p-value	Adjusted Mean VFCH12M
FACTORS				
Ocular Comorbidity (OH) :	2.47 [-0.54 to 5.47]	0.11		OH absent 27.05 present 22.11
Second Eye Surgery (E212M) :	-4.70 [-7.66 to -1.74]	0.002		E212M no 19.88 yes 29.28
OH by E212M :	-0.86 [-3.81 to 2.09]	0.56		OH=0, E212M=0 21.48 OH=0, E212M=1 32.61 OH=1, E212M=0 18.27 OH=1, E212M=1 25.95
COVARIATES				**Average R-squared**
Pre-Operative Better Eye Visual Acuity (BVHI) :	-4.61 [-6.11 to -3.1]	-0.35	<0.001	0.47
Age on Admission :	-0.51 [-0.81 to 0.21]	-0.19	0.001	0.07

* Squared correlation between covariates and predicted VFCH12M

R-Square = 0.197
Model Adjusted R-squared = 0.181

The tests for homogeneity of variance gave p-values of 0.296 and 0.170. These together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid (Appendix D4).

b. Using change in better eye visual acuity after surgery

This model was fitted as before but used change in better eye visual acuity as a covariate instead of pre-operative better eye visual acuity. The findings at 4 months are presented in Table 8.21 and in Table 8.22 for those at 12 months.

These models explained more of the variability of change in visual function after surgery. At 4 months after surgery 13.8% of this variabilty was explained (R-square = 0.138; model adjusted R-square = 0.127), and at 12 months 30.8% was explained (R-square = 0.308; model adjusted R-square = 0.291).

Ocular comorbidity was not a significant factor influencing the relationship between change in visual function and change in better eye visual acuity after surgery. However at 12 months second eye surgery was a significant factor after adjusting for the other variables. The combined adjusted mean change for visual function was significantly higher when second eye surgery was performed (27.77 v 19.98). There was no significant interaction term whereby the association between second eye surgery and change in visual function might depend on levels of ocular comorbidity (the interaction p-value =0.882).

Having controlled for the effects of the other variables in the model, change in better eye visual acuity was a significant covariate associated with change in visual function after surgery. As more change in better eye visual acuity was achieved, then on average, more change in visual function was gained (regression coefficient = 5.18 at 4 months, and 6.82 at 12 months). Age remained a significant covariate, indicating that, having controlled for the other variables, as age increased, then on average less change in visual function was achieved post-operatively (regression coefficient = -0.40 at 4 months, and -0.43 at 12 months).

Table 8.21 Change in Visual Function 4 MONTHS after surgery and Change in Better Eye Visual Acuity at 4 Months

ANOVA : 241 cases with complete data

Variables in Model		Coefficient	[95% C.I]	beta	p-value	Adjusted Mean VFCH12M
FACTORS						
Ocular Comorbidity (OH) :		-1.12	[-3.93 to 1.70]		0.44	OH absent 19.25
						present 21.49
COVARIATES						**Average R-squared ***
Change in Better Eye Visual Acuity	:	5.18	[3.44 to 6.91]	0.36	< 0.001	0.84
Age on Admission	:	-0.40	[-0.72 to -0.08]	-0.15	0.014	0.07

* Squared correlation between covariates and predicted VFCH4M

R-Square = 0.138
Model Adjusted R-squared = 0.127

The tests for homogeneity of variance gave p-values of 0.727 and 0.751. These, together with analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid (Appendix D3).

Table 8.22 **Change in Visual Function 12 MONTHS after surgery (VFCH12M) and Change in Better Eye Visual Acuity**

ANOVA : 210 cases with complete data

Variables in Model	Coefficient	[95% C.I]	beta	p-value		Adjusted Mean VFCH12M
FACTORS						
Ocular Comorbidity : (OH)	1.85	[-1.29 to 4.99]	0.246		OH absent	25.72
					present	22.02
Second Eye Surgery : (E212M)	-3.89	[-7.04 to - 0.75]	0.015		E212M no	19.98
					yes	27.77
OH by E212M :	-0.23	[-3.34 to 2.88]	0.882		OH=0, E212M=0	21.59
					OH=0, E212M=1	29.85
					OH=1, E212M=0	18.36
					OH=1, E212M=1	25.68
COVARIATES						**Average R-squared ***
Change in Better Eye Visual Acuity at 12 months (BVCH12M) :	6.82	[5.14 to 8.49]	0.47	<0.001		0.791
Age on Admission :	-0.43	[-0.74 to -0.12]	-0.16	0.007		0.058

* Squared correlation between covariates and predicted VFCH12M

R-Square = 0.308
Model Adjusted R-squared = 0.291

The tests for homogeneity of variance gave p-values of 0.242 and 0.081. These together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid. (Appendix D4).

Clearly there are other factors influencing or determining the change in visual function achieved post-operatively as pre-operative better eye acuity and change in better eye acuity post-operatively can only explain a small proportion of the variability in change in visual function achieved after surgery. It must also be noted that from the analysis of pre-operative visual function scores, poorer pre-operative better eye visual acuity was associated with lower pre-operative visual function scores and thereby having more capacity for change (particularly in the direction of gain), post-operatively. Similarly, pre-operative visual function scores were higher (less reported dysfunction) with increasing age, thereby reducing the capacity for change (particularly for gain), with age. Both pre-operative better eye visual acuity and age are determinants of pre-operative visual function score. Consequently, pre-operative visual function not only influences the capacity for change possible after surgery, but it may also possibly confound the relationships observed between change in visual function and visual acuity (both pre-operative better eye acuity and change in better eye acuity post-operatively). Whilst this may not be of primary concern when considering the validity of the findings regarding the overall relationship between change in visual function after cataract surgery and visual acuity, it is important in the interpretation of the findings for the determinants of change in visual function after surgery.

4.3.2 Determinants of change in visual function after surgery adjusting for the capacity for change

The following models were then constructed to identify the determinants of change in visual function after cataract surgery, taking account of the capacity for change possible after surgery and possible confounding factors. As before, the relationships at 4 months and 12 months were considered in separate models and full details provided in Appendices D3 and D4.

a. Model 1 : Determinants of change in visual function operating through visual acuity

Assessing the influence of (or association of) factors and covariates on change in VF-14 scores after surgery (4 months and 12 months), **including** the component of the influence (association or correlation), if any, that might operate through "causing" loss or gain in visual acuity.

This ANOVA model included pre-operative visual function score (VFSD), pre-operative better eye visual acuity (BVHI) and age as covariates, with ocular comorbidity as a factor. The term for change in better eye visual acuity (**BVCH4M** at 4 months and **BVCH12M** at 12 months), was **omitted** from this model, so that any estimates of factor effects would include the effect on visual acuity change (if any) which in turn affected change in the VF-14 score.

The findings at 4 months are summarised in Table 8.23 and in Table 8.24 for those at 12 months.

The findings show that after adjustment of the other variables in the model, ocular comorbidity was not a significant factor determining change in visual function score at 4 months after surgery. However at 12 months, ocular comorbidity (OH) and second eye surgery by 12 months after first extraction, were significant factors, suggesting that these might be determinants of change in visual function, after adjustment for effects of the other variables in the model. The combined adjusted mean change in visual function at 12 months for patients with no ocular comorbidity was substantially (and significantly) higher than that in patients with comorbidity (27.45 v. 21.70).

Similarly, the mean gain in visual function was greater in patients who had second eye surgery compared to those who had not (26.89 v. 22.27). Further breakdown of the adjusted mean change in visual function scores at 12 months showed that the greatest gain in visual function (30.24) occurred in the sub-group who had no ocular comorbidity but had second eye surgery, and the least gain in visual function (19.87) occurred in those who did have ocular comorbidity but did not have second eye

surgery. There was no significant interaction whereby the association of ocular comorbidity with change in VF-14 score at 12 months, might depend upon levels of whether second eye surgery was performed or not, or whereby the second eye surgery and change in VF-14 score at 12 months association might depend upon whether or not comorbidity was present (the interaction p-value was 0.629).

The pre-operative visual function score was found to be a significant and powerful covariate influencing change in visual function after surgery. The findings show that at 4 months 96% of the variation in the change in visual function scores (as predicted by the model) was "explained" by the variation in pre-operative visual function score, and at 12 months this was 92%. The negative regression coefficients (-0.75 at 4 months and -0.79 at 12 months), indicated that patients with higher initial pre-operative visual function scores on average gained less visual function. The correlation was characterised by a reduction in change in visual function of 0.75 units or 0.79 units (at 4 and 12 months respectively) for each unit increase in pre-operative visual function score. The standardised coefficient, beta, was by far the greatest compared to that of the other two covariate variables in the models. The data suggest that pre-operative visual function score may be an important "determinant" of the amount of gain or loss in visual function after surgery.

The pre-operative visual acuity in the better eye before surgery was also found to be a significant variable that influences the change in visual function gain after surgery. The data suggested that patients with better initial visual acuity tend on average to gain more visual function after surgery. The correlation was highly significant but not impressive since only a small fraction (14%) of the variation in change in visual function at both 4 and 12 months was "explained" by the variation in pre-operative better eye visual acuity.

Age was not a significant covariate. The findings suggested that when the effects of the other variables in the models were taken into account and adjusted for, the amount of gain or loss in visual function after surgery was not dependent upon age at surgery,.

Table 8.23 **Change in Visual Function 4 MONTHS after surgery (VFCH4M) and Pre-operative Better Eye Visual Acuity - Adjusting for Pre-operative Factors**

ANOVA : 272 cases with complete data

Variables in Model	Coefficient	[95% C.I]	beta	p-value	Adjusted Mean VFCH4M
FACTORS					
Ocular Comorbidity (OH) :	0.61	[-1.30 to 2.52]		0.533	OH absent 20.63
					present 19.42
COVARIATES					**Average R-square**
Pre-Operative VF-14 Score : (VFSD)	-0.75	[-0.84 to -0.66]	-0.81	<0.001	0.96
Pre-Operative Better Eye Visual Acuity :	2.02	[0.66 to 3.39]	0.16	0.004	0.14
Age on Admission :	-0.09	[-0.31 to 0.14]	0.11	0.44	0.01

* Squared correlation between covariates and predicted VFCH4M

R-Square = 0.539
Model Adjusted R-squared = 0.532

The tests for homogeneity of variance gave p-values of 0.763 and 0.779. These, together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid (Appendix D3).

Table 8.24 **Change in Visual Function 12 MONTHS after surgery and Pre-operative Better Eye Visual Acuity, Adjusting for Pre-operative Factors.**

ANOVA : 261 cases with complete data

Variables in Model	Coefficient [95% C.I]	beta	p-value	Adjusted Mean VFCH12M	
FACTORS					
Ocular Comorbidity (OH) :	2.88 [0.90 to 4.85]		0.004	OH absent	27.45
				present	21.70
Second Eye Surgery (E212M) :	-2.31 [-4.26 to - 0.35]		0.021	E212M no	22.27
				yes	26.89
OH by E212M :	-0.47 [-2.4 to 1.46]		0.629	OH=0, E212M=0	24.67
				OH=0, E212M=1	30.24
				OH=1, E212M=0	19.87
				OH=1, E212M=1	23.53
COVARIATES				**Average R-squared ***	
Pre-Operative VF-14 Score(VFSD) :	-0.79 [-0.87 to -0.70]	-0.84	< 0.001	0.92	
Pre-Operative Better Eye Visual Acuity (BV) :	1.74 [0.55 to 2.94]	0.13	0.004	0.14	
Age on Admission :	-0.1 [-0.30 to 0.10]	-0.04	0.327	0.02	

* Squared correlation between covariates and predicted VFCH12M

R-Square = 0.656
Model Adjusted R-squared = 0.648

The tests for homogeneity of variance gave p-values of 0.296 and 0.170. These together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid. (Appendix D4)

It is important to note here that assuming a causal relationship, the significant influence of ocular comorbidity and second eye surgery within 12 months upon change in visual function may be partly (or even entirely) mediated through gain or loss in visual acuity. For example, does second eye surgery result in higher gain in visual function because it causes further improvement in best visual acuity? Or, does it result in higher gain in visual function because of improvement in some other aspect of visual function over and above that of visual acuity? Or both?. Similar questions may be asked in respect of all the other significant variables reported above. The next section of the analysis addresses these questions.

b. Model 2 : Determinants of change in visual function excluding the influence operating through visual acuity

Assessing the influence of (or association of) factors and covariates on change in visual function after surgery, **excluding** the component of the influence (association or correlation), if any, that might operate through "causing" loss or gain in visual acuity.

To achieve this, the term for change in better eye visual acuity after surgery (**BVCH4M** at 4 months and **BVCH12M** at 12 months), were now **included** in the ANOVA model, so that any estimates of factor effects would exclude the effect on visual change (if any) which in turn affected change in visual function score.

The findings at 4 months are summarised in Table 8.25 and in Table 8.26 for those at 12 months.

Table 8.25 **Change in Visual Function 4 MONTHS (VFCH4M) after surgery and Change in Better Eye Visual Acuity - Adjusting for Pre-operative Factors**

ANOVA : 241 cases with complete data

Variables in Model		Coefficient	[95% C.I.]	beta	p-value	Adjusted Mean VFCH4M
FACTORS						
Ocular Comorbidity (OH) :		-0.40	[-2.28 to 1.47]	0.67		OH absent 19.96 present 20.77
COVARIATES						**Average R-square**
Pre-Operative VF-14 Score : (VFSD)		-0.81	[-0.90 to -0.72]	-0.87	< 0.001	0.815
Pre-Operative Better Eye Visual Acuity (BVHI)	:	7.19	[5.38 to 9.01]	0.55	< 0.001	0.105
Change in Better Eye Visual Acuity at 4 Months (BVCH4M)	:	6.48	[4.79 to 8.17]	0.45	< 0.001	0.18
Age on Admission	:	-0.03	[-0.24 to 0.19]	-0.01	0.803	0.016

* Squared correlation between covariates and predicted VFCH4M

R-Square = 0.64
Model Adjusted R-squared = 0.634

The tests for homogeneity of variance gave p-values of 0.727 and 0.751. These, together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid (Appendix D3).

Table 8.26 **Change in Visual Function 12 MONTHS after surgery and Change in Better Eye Visual Acuity, Adjusting for Pre-operative Factors**

ANOVA : 21O cases with complete data

Variables in Model	Coefficient [95%C.I]	beta	p-value		Adjusted Mean VFCH12M
FACTORS					
Ocular Comorbidity : (OH)	0.96 [-0.74 to 2.67]	0.267		OH absent	24.84
				present	22.91
Second Eye Surgery : (E212M)	-1.92 [-3.59 to -2.4]	0.025		E212M no	21.95
				yes	25.79
OH by E212M :	0.53 [-1.13 to 2.19]	0.529		OH=0, E212M=0	23.45
				OH=0, E212M=1	26.23
				OH=1, E212M=0	20.45
				OH=1, E212M=1	25.36
COVARIATES					**Average R-squared ***
Pre-Operative VF-14 Score (VFSD) :	-0.85 [-0.92 to -0.77]	-0.88	<0.001		0.79
Pre-Operative Better Eye Visual Acuity (BVHI) :	7.37 [5.92 to 8.82]	0.54	<0.001		0.13
Change in Better Visual Acuity at 12 months (BVCH12M) :	7.53 [6.22 to 8.83]	0.52	<0.001		0.301
Age on Admission :	0.08 [-0.09 to 0.26]	0.03	0.358		0.022

* Squared correlation between covariates and predicted VFCH12M

R-Square = 0.808
Model Adjusted R-squared = 0.802

The tests for homogeneity of variance gave p-values of 0.242 and 0.081. These together with the analysis of residuals suggested that no serious violations occurred and that the ANOVA analysis was valid (Appendix D4).

The findings show that after adjustment for effects of other variables in the model, ocular comorbidity was not a significant factor. Second eye surgery was however a significant factor, suggesting that it might be a determinant of change in VF-14 score, after adjustment for the effects of the other variables in the model. The combined adjusted mean change in visual function for patients that had second eye surgery was significantly higher than those who did not have second eye surgery (25.8 v. 21.9). The combined adjusted mean change in visual function score was higher (but not significantly) for patients without ocular comorbidity than for those with comorbidity (24.8 v. 22.9). There was no significant interaction term whereby the association of second eye surgery with change in visual function score at 12 months might depend on levels of ocular comorbidity, or whereby the association of ocular comorbidity with change in visual function score at 12 months might depend upon whether second eye surgery had been performed or not (the interaction term p-value = 0.529).

Age was not a significant covariate for change in visual function after surgery. The nature of the relationship between change in visual function score after surgery and change in better eye visual acuity after surgery and pre-operative visual function score, was examined for any departures form linearity, and interactions with ocular comorbidity and sex were sought. In the case of the model for the relationships at 12 months, whether second eye surgery had been performed or not by this time was also included. No significant interactions were demonstrated to suggest violations from linearity in the important relationships demonstrated.

The pre-operative visual function score was found to be a significant and powerful covariate. 82% of the variation in the change in visual function scores at 4 months (as predicted by the model), and 79% of the variation observed at 12 months was "explained" by the variation in the pre-operative visual function scores. The negative regression coefficients (-0.81 at 4 months and -0.85 at 12 months) indicate that patients with a higher initial visual function score before surgery gained less visual function on average, after surgery.

Visual acuity in the better eye before surgery was also a significant variable that may affect the gain in visual function after surgery. It explained about 10% of the variation in change in visual function scores at 4 months and 14% at 12 months. The positive regression coefficients at both 4 and 12 months indicate that patients with better initial visual acuity in the better eye before surgery tend on average to gain more visual function after surgery. The correlation was characterised by a gain in visual function of 7.2 units at 4 months and 7.53 units at 12 months, for each unit increase in pre-operative better eye visual acuity.

The amount of change in visual acuity in the better eye after surgery was also found to be a significant covariate. 18% of the variation in the change in visual function score at 4 months and 30% of the variation at 12 months was "explained" by the change in better eye visual acuity after surgery. The positive regression coefficient indicates that for every unit increase in change in visual acuity in the better eye after surgery at 4 months, a change 6.5 units in visual function score on average could be predicted from the model. Similarly for a change in unit increase in visual acuity at 12 months, a change of 7.5 units on average could be predicted from the model.

The estimates from the full model may be used to predict change in visual function at 12 months from pre-operative visual function and the change in better eye visual acuity at 12 months.

5. DISCUSSION OF FINDINGS

The relationships between clinical and patient perceived measures i.e. visual acuity, visual function and quality of life, have been presented.

5.1 Visual Acuity

As measures of visual acuity, the VP% score and better eye acuity were highly correlated before and after surgery. As the calculation of the VP% score is weighted in favour of the better eye acuity this is not surprising. Both VP% score and better eye acuity consistently had higher correlations (both before and after surgery) with visual function (VF-14) and measures of quality of life (SIP and VR-SIP), compared to the surgery eye acuity. The VP% score did not improve on better eye acuity in its correlations with visual function score (VF-14), and measures of quality of life (SIP and VR-SIP), either before or after surgery, and the better eye visual acuity was consistently slightly better. These findings suggest that better eye acuity and VP% score (visual acuity of the person), better represent the visual acuity that is used in everyday life, both before and after surgery. As shown earlier, whilst surgery eyes are often the better eyes after cataract extraction, they do not represent *all* the better eyes after surgery.

The association with visual acuity and other measures of outcome has not been considered in this way previously. Whilst it may have been recognised that the visual input from both eyes should be considered when assessing the disability from cataract, and that the better eye visual acuity should also be considered,[103] this concept has rarely been used to relate visual acuity with function or quality of life, beyond an assessment of the criterion validity of these latter measures.[103][136] More often in such assessments, it has been the *visual acuity in the surgery eye* (both before and after surgery) that has been used i.e. the clinical indicator of outcome and its associations if any, with visual function and quality of life before surgery.

[88][104][107][162] After surgery, any association with function and quality of life has so far been considered in terms of the visual acuity in either the surgery eye or the better eye before surgery [163], and more recently, with a weighted visual acuity (derived from the visual acuity from each eye separately) to take account of both eyes [156][164]. The role of the better eye acuity on everyday life has not been previously appreciated.

Best corrected better eye visual acuity is a readily available measure of visual acuity and does not require additional computations or interpretations of the measurement. It was thus used in all further analysis for examining the relationships between visual acuity and visual functioning in vision-dependent activities and health and vision-related quality of life, before and after surgery.

5.2 Visual Function

5.2.1 Relationships Before Surgery

There was a wide variation about the mean VF-14 scores for any given sub-group of visual acuity considered, suggesting that multifactorial influences may have been operating on the reported level of visual functioning ascertained before surgery.

A linear relationship with visual acuity in the better eye before surgery was described that explained about 30% of the variability in the pre-operative visual function scores observed. Clearly other factors were also influencing pre-operative functioning. Such a relationship had been alluded to previously but it had not been quantified [103]. Whilst a relationship with visual acuity had been anticipated at the start of this study, a perfect relationship had not been expected. This is because the VF-14 index is a measure of functioning in everyday tasks dependent on *vision*, and visual acuity is only *one* component of vision.

A multiple regression model including other factors that may have been influencing visual functioning was able to make only a slight improvement in explaining the variability of pre-operative VF-14 scores - 38%. Clearly the VF-14 score was influenced by other factors not examined in this study. The independent determinants of pre-operative visual function that were identified from these data, were -

Visual acuity in the better eye before surgery

Cataract symptoms

Comorbidity "bothersome-ness"

Age

Adjusted estimates, controlling for the effects of the other variables in the model, suggested an inverse relationship between cataract symptoms and how bothered patients were by their other comorbidities. The more that patients were bothered by their cataract symptoms or their other comorbidities, the worse was their reported visual function.

Visual function scores rose with increasing age. The relationship with age could not be directly explained. Since the VF-14 score is composed of the reported difficulty in performing a vision-dependent activity and also the amount of difficulty experienced in performing it, it would seem that with increasing age there is less reporting of the difficulty experienced with performing the activities in question. It is possible that this may reflect a period of adaptation and disengagement in the older age group - they may be still doing an activity e.g. reading, but not as much as before, because of their vision, and thus can still function in that respect (albeit with a limited capacity), to their satisfaction. Younger patients may not have adapted their activities to this extent and are more aware of the limitations imposed on them in this respect by their vision. Similarly, it is possible that these influences are operating in the finding that younger patients have higher cataract symptom complaints than the older patients. It is possible that older patients may have the same symptoms but that they are not as aware of the consequences of these symptoms because they have had the for longer

and adapted their lifestyle accordingly. This study design and its findings can only speculate or generate hypotheses regarding these issues. Further exploration and examination of these issues, and possibly other related factors influencing initial VF-14 score are beyond the scope of this study design and data set and require specific investigation.

5.2.2 Relationships After Surgery

The variation in VF-14 scores across sub-groups of visual acuity in the better eye persisted post-operatively as seen by the spread of scores about the mean VF-14 score for any visual acuity group. The crude relationships between change in VF-14 scores and pre-operative VF-14 score, pre-operative better eye visual acuity and change in better eye visual acuity after surgery, demonstrated the presence of linear associations between them.

Multiple regression models adjusting for the effects of indicators as determinants of change in visual function after surgery, identified pre-operative visual function score as a major determinant of change in visual function, with pre-operative better eye visual acuity and change in better eye acuity after surgery also being important determinants of change in visual function. The regression models adjusted for the effects of all the other variables in the model (i.e. adjusting for confounding), thus allowing for the effect of each of the indicators as determinants of change in VF-14 score, in their own right, to be assessed.

The most striking observation was the identification of confounding by pre-operative visual function which was seen in the reversal in the regression coefficients for pre-operative better eye visual acuity and change in visual function after surgery. Crude analysis had suggested that patients with poorer pre-operative better eye acuity tended on average to gain more visual function after surgery. However when the effects of other variables and the capacity for change (pre-operative visual function score) were adjusted for in the regression model, then patients with better visual acuity in the better eye before surgery tended on average to gain more visual function after surgery.

Similarly pre-operative visual function confounded the relationship between age and change in visual function after surgery. Crude analysis had suggested that with increasing age, then on average there was less change in visual function after surgery. When the capacity for change that was possible was adjusted for, together with other confounding variables, then age was not seen to be a significant determinant of change in visual function after surgery.

The crude relationship observed between pre-operative better eye acuity and change in visual function post-operatively, and that between age and change in visual function was spurious. As shown earlier, patients with poorer pre-operative visual acuity have poorer initial visual function before surgery, and older patients tended to have better reported visual function. Also, pre-operative visual acuity and age were determinants of visual function before surgery. The crude relationship (unadjusted for capacity for change) observed between change in visual function and pre-operative visual acuity in the better eye on the one hand, and age on the other hand, was thus being confounded by pre-operative visual functioning.

Model 1 provided indicators for change in visual function after surgery when the effects working through vision were included. ***Model 2*** provided indicators for change in visual function after surgery when the effects on vision working through gain or loss in visual acuity were excluded. Overall when components operating through visual acuity were removed , the regression coefficients were larger. The variables for change in better eye visual acuity at 4 or 12 months (BVCH4M and BVCH12M), took account of the fact that everyone did not start at the same level of visual acuity. (Proportional changes in visual acuity were considered but as they were highly correlated with change in better eye acuity variables (BVCH4M and BVCH12M), only the latter were used in all further analysis). By adjusting for the effects of confounding between pre-operative visual function and pre-operative better eye visual acuity, the models could predict the mean change in visual function that may be expected for a unit change in better eye visual acuity after surgery, and the mean change in visual function that may be expected for unit change in pre-operative visual function.

At both 4 and 12 months, pre-operative visual function was a major determinant of change in visual function after surgery (operating both through any effects on vision working through visual acuity and independent of visual acuity). Patients with better (less dysfunction) pre-operative visual function on average gained less visual function after surgery. For any given level of visual functioning pre-operatively, the multiple regression models suggest that those patients with better pre-operative visual acuity in the better eye, gain on average, more visual function after surgery. This would suggest that more gain, in terms of visual functioning, is achieved if, for a given level of reported functioning, intervention takes place before visual acuity in the better eye becomes significantly compromised. Thus if surgery was performed on a patient with both eyes that were visually impaired, then despite achieving a good visual acuity outcome in the surgery eye, the gain in visual function that could be achieved would not be as great as that in a patient that had surgery performed on a visually impaired eye with a fellow (better) eye that was not impaired, had both patients had an equivalent level of reported visual functioning to begin with.

Ocular comorbidity was a significant factor influencing the association between covariates and change in visual function exerted its effect primarily through its effect on visual acuity and this was seen only at 12 months after surgery. Second eye surgery by 12 months after surgery was also a significant factors influencing the association between covariates and change in visual function at 12 months, operating through both its effect on vision through visual acuity and independently of visual acuity. In the latter case, second eye surgery presumably influenced gain in visual function (change in VF-14 score) through some other aspect not mediated solely by Snellen visual acuity e.g. better field, binocularity, or stereopsis that may have been achieved by second eye surgery. For a given covariate, the mean change in visual function will depend on the level of the factor - i.e. for a given covariate, the mean change in visual function will be greater if there is no ocular comorbidity present and if second eye surgery has been performed.

The assessment of visual function is subjective. It will depend not only objective measures such as visual acuity, but also many other complex influences e.g. social, cultural, expectations of function and adaptation of lifestyle with age. These are presumably also operating here as seen pre-operatively, older patients tend to have higher visual function scores, lower cataract symptom scores and comorbidity "bothersome" scores. The findings from this study can only speculate that this observation may be a result of these other factors. Only a specifically designed study examining these factors could reasonably expect to ascertain a more conclusive explanation of these observations and their influence on function.

Over 80% of all patients achieve a good post-operative visual acuity of 6/6 to 6/12, at 4 and 12 months. Similarly, over 80% of patients achieve a post-operative visual function scores of 80 or more with a third achieving a maximum score of 100. Overall, the gains in the routine clinical indicator (Snellen visual acuity) reflect the gains achieved in visual function. The discrepancy first described by Bernth-Petersen for intracapsular cataract extraction 25 years ago, is now not as evident. [82][104][107][162] This is not surprising as most of the earlier differences between visual acuity and visual function were caused by the limitations of the optical correction of aphakia and their incumbent optical aberrations, that were available at that time. Current surgical practice and optical rehabilitation with intra-ocular lenses have overcome these difficulties so any effect on visual functioning that is operating through visual acuity is now not seen.

Assessment of visual function also provided insight into the benefits from cataract surgery that were not apparent by assessment of visual acuity alone. Patients with poor visual acuity outcome were observed to achieve significant mean gains in VF-14 score. It is likely that these patients may have achieved some improvement in acuity after surgery but they did not achieve an acuity of 6/12 or better. They may have gained improvement in visual function though some other component of vision e.g. through gain in visual field, binocularity or stereopsis. Assessment of outcome by the conventional clinical indicator of visual acuity would not have identified the benefits of cataract surgery for these patients. Although there are objective clinical measures and

tests for the assessment of visual field, binocularity or stereopsis, that are available in any ophthalmic department, these are not routinely assessed before or after cataract surgery.

5.3 Quality of Life

The major determinant of the overall SIP score was the comorbidity "bothersome" score indicating that quality of life was influenced principally by other health factors . Visual function score was the major determinant of the quality of life affected by vision (VR-SIP score) indicating that in this case the level of reported disability was associated with the handicap experienced.

6. Summary of Findings

The key findings relating to the relationships between visual acuity, visual function and quality of life are :

- The appropriate measure of visual acuity should be selected for examining relationships between measures of outcome (clinical and patient perceived)

- The best corrected *surgery* eye visual acuity reflects the visual impairment caused by cataract and the direct effect of surgery on this

- The best corrected *better* eye visual acuity is the visual acuity which is operating in everyday life for vision-dependent activities and quality of life.

- Visual acuity in the better eye is linearly related to visual function and is an important determinant of pre-operative visual function after surgery

- Visual function assessment before surgery may be underestimated in older patients

- Quality of life in cataract patients was not greatly affected by their vision

- Quality of life amongst cataract patients was determined by their medical comorbidity

- Change (gain) in better eye visual acuity was associated with change (in direction of gain) in visual function

- Adjustment for the capacity for change in both visual function and visual acuity identified important effects from confounding by pre-operative visual functioning :

  For a given level of visual functioning, better visual acuity in the better eye before surgery was associated with more gain in visual function may be achieved

  Change in visual function after surgery was not age-related.

- Ocular comorbidity was not a significant factor influencing the relationship between visual acuity and visual function except at one year after surgery

- Second eye surgery was an important factor influencing the relationship between visual acuity and change in visual function after surgery

- The impact of cataract surgery on change in visual function was achieved both through effects on vision mediated by visual acuity, and through effect on vision not mediated by visual acuity.

Chapter 9.

CONCLUSIONS

The outcomes of cataract surgery have been assessed in terms of clinical measures of impairment (visual acuity), and patient perceived measures of disability (visual function) and handicap (quality of life). This thesis suggests that whilst age related cataract is associated with impairment and disability, the strength of the relationship with handicap is weaker. Surgery has been seen to improve visual acuity, visual function and quality of life. The findings have contributed to understanding the effect of cataract on visual impairment, disability and handicap, and the impact of surgery on these.

Understanding the inter-relationships between visual acuity, visual function and visual handicap can inform the interpretation of the impact of the gains observed following surgery. In this chapter, the use of the methods employed in this thesis both for clinical practice (patient-based) and for epidemiological purposes (population-based) for the evaluation of the impact of cataract surgery are discussed.

1. Methods for the Assessment and Measurement of Impairment, Disability and Handicap

The definition of cataract used in this thesis was an operational one, based on a need for surgery that was recognised by both the patient and his or her ophthalmic surgeon. This inevitably resulted in patients with a wide range of severity of visual impairment, even including some with only minimum loss of acuity. This is in contrast to that used in many aetiological studies where the earliest onset of cataract (which may not

necessarily be associated with impairment or disability), is often of interest. Also, from the start it was recognised that both eyes contribute to the biological functioning of the eyes and social functioning in everyday life and that this would need to be considered when assessing the impact both of cataract and of surgery on one eye.

Clinical impairment was measured by visual acuity using the Snellen optotype. Patient perceived methods were used to measure disability (visual function) and handicap (quality of life). The VF-14 was used for visual function and SIP and VR-SIP were used for quality of life.

1.1 Visual Acuity

Visual acuity is a recognised indicator of vision. Snellen visual acuity is well-established and is routinely employed in clinical practice as part of the basic clinical examination of any eye disorder. Its limitations and interpretation of change in visual acuity over time or following treatment are recognised. The findings of this thesis indicated that the visual acuity from each eye provided quite different information. The visual acuity in the affected eye indicated the impairment caused by cataract and subsequently the direct impact of surgery on this. The relationships between visual acuity, visual function and quality of life, suggested that the visual acuity of the better eye provided a better indication of the vision that was used in everyday life (disability), and to a much lesser extent the handicap experienced by the patient. Visual acuity in the better eye was observed to be a major determinant of visual function before surgery. The strength of this relationship reflected the fact that visual acuity is only one component of overall vision that is required in everyday life. The quality of life of cataract patients was affected more by how bothered they were by their comorbid conditions rather than by their vision. After surgery, change in better eye visual acuity was associated with change in visual function and was a significant determinant of change in visual function.

These findings suggest that visual acuity, as a measure of impairment was an *indicator* of disability, and to a lesser extent handicap. The surgery eye visual acuity indicated the impairment caused by cataract while the better eye visual acuity served as a proxy indicator of the disability and/or handicap caused by cataract. This suggests the need for a significant shift from the traditional clinical approach which has been based on the impact of cataract and surgery on the visual acuity in the affected eye. Previously, only the visual acuity in the affected (surgery) eye had been considered and had been found to be poorly related to disability and handicap, especially after surgery. The role of the ***better eye acuity*** in everyday life, particularly ***after surgery***, had not previously been examined or recognised.

1.2 Visual Function

The VF-14 was found to be a valid (face and criterion validity) and reliable (internal consistency) index of visual functioning in cataract patients. The variability in the VF-14 scores observed before surgery suggested that there were multifactorial influences determining the reports of visual function. The VF-14 represents the patients' *perception* of their visual functioning, and not necessarily their *actual* functioning. Whilst some of the possible factors determining reported visual function were considered in this thesis, there were others (e.g. duration of symptoms, adaptation), that may have had important contributions to reported functioning, that were not. Until the influence of these other factors are understood, the implications of visual function scores for clinical practice are limited.

Whilst some form of assessment of disability (visual function) is usually made in routine clinical practice it is not usually undertaken in a standard and validated form that may be used to compare patients or to assess the impact of surgery on an individual. The VF-14 represents just such a method for standardising this assessment in clinical practice. Although self-completion of the VF-14 by patients was not tested this may be feasible. It is possible however that, at least before surgery self-

completion would pose problems for those patients who are severely visually impaired. In such circumstances, the quality of proxy information for the VF-14 in terms of completeness and accuracy, has still to be established. The findings suggest that the VF-14 may be a useful tool for assessing disability in cataract patients both in routine clinical practice and in health services research.

1.3 Quality of Life

Both the SIP and VR-SIP demonstrated criterion validity for measuring quality of life of cataract patients. Quality of life of cataract patients was seen to be affected more by their comorbid conditions than by their vision. Only a limited range of categories of quality of life were affected, principally "recreation and pastimes". The items covered in this category provided the quality of life component to complement the functional index, the VF-14. Given that vision was not a major factor affecting quality of life, it was not surprising that the modified generic measure, the VR-SIP, did not show any improvement over the generic measure (SIP).

This thesis identified the limited impact of elective cataract surgery on patients' overall quality of life, and the extent of change which may realistically be expected. If a more precise assessment of the quality of life of cataract patients is required, it may be more appropriate to develop a cataract-specific quality of life measure tapping into the most relevant categories (e.g. recreation and pastimes, and perhaps work and home management). This would, however, require further research, development and evaluation before being available for use either for routine practice or for research.

1.4 Interpretation of the Gains in Visual Function and Quality of Life

Overall, significant mean gains in the patient perceived measures of visual function and quality of life were demonstrated after surgery compared to pre-operative values. Whilst the value of patient perceived measures in providing insight into the impact of disease on a patient's daily life has received attention, the clinical significance of the impact of an intervention as assessed by these measures has received considerably less attention. A universal definition of the amount of change in say, quality of life measured by the SIP, that constitutes a clinically important change, is unlikely. For cataract patients no data are available on what constitutes clinically or socially significant changes in visual function and quality of life, using either the instruments employed in this study, or for other similar patient perceived measures.

Effect size was used to assess responsiveness to change and also the amount of change that may be clinically and socially important. Based on the magnitude of change and the effect sizes observed, the likely level of change in quality of life and visual function that may be socially significant was shown to be a change of 3 units in the SIP score, 1.3 units in the VR-SIP score, and less than or equal to 20 units in the VF-14 score. These need to be confirmed in other samples of cataract patients.

2. IMPLICATIONS FOR CLINICAL PRACTICE

The patient perceived measures of visual functioning and quality of life have provided insight and complementary information to visual acuity for the assessment of the outcomes of cataract surgery. This has several implications for clinical practice.

2.1 Influence of advances in optical correction of aphakia on the outcome of surgery

Despite advances in both surgical technique and in the optical correction of aphakia provided by intraocular lenses, there has not been any significant improvement in clinical outcome (as measured by visual acuity), in the surgery eye over the last two decades. About 80% of patients achieve a good visual acuity irrespective of type of procedure or type of optical correction. [81][82][83][84][85] The findings from this thesis indicate that the discrepancy between post-operative visual acuity in the surgery eye and visual function that was first described at least 15 years ago,[81] has now been considerably narrowed. Although the measure of visual function used at that time may not be directly comparable with the VF-14, both indices have a similar content. About 80% of patients now achieve good visual acuity and 80% now also achieve good visual function. This is probably a result of posterior chamber intraocular lenses for optical correction after cataract extraction. They are able to provide a better quality of vision as they are not burdened by the problematic optical aberrations associated with the optical correction available before the introduction of microsurgical techniques and intraocular lens implantation.

Visual acuity assessment alone was not able to detect the impact of better quality of vision that may be obtained from intraocular lens implants on patients' functioning. Anecdotally, this may have been acknowledged clinically, but had not been explicitly expressed before in these terms.

2.2 Improved identification of the benefits of cataract surgery

Significant gains in visual function and quality of life were observed in the group of patients who did not achieve good visual acuity (6/12 or better). A third of the patients having cataract surgery had ocular comorbidity in the surgery eye, and were found to be at greater risk of having a poor visual acuity outcome than patients

without ocular comorbidity. The traditional clinical indicator of visual acuity alone would have underestimated the benefit of surgery to a significant proportion of patients.

2.3 Gains in visual function from effects on vision not operating through, nor measured by visual acuity.

Analysis of the determinants of change in visual function clearly demonstrated that gains were achieved not only through effects on vision operating through visual acuity but also through other effects on vision. This reflected the fact that visual acuity is only one component of vision influencing function. Other components of vision that may influence visual function that are not directly measured by visual acuity include binocularity, stereopsis, and visual field. There are objective clinical tests available to measure these but they are not routinely used in the assessment of cataract patients either before or after surgery. The relationships between visual function and quality of life and these other components of vision need to be investigated further.

2.4 The Contribution of Second Eye Surgery to Outcome

A third of the cataract surgical workload is taken up by second eye surgery. The thesis has demonstrated the *additional* contribution of second eye surgery to outcome. Significant gains in visual function and quality of life beyond those gained after first eye surgery were demonstrated. The gains in visual function were achieved through effects on both visual acuity, and other components of vision. These findings support the value of second eye surgery which other studies have reported. [168][169]

2.5 Timing of intervention for maximising benefit

The concept of the potential "capacity for change" as a result of surgery takes account of the fact that not all patients have the same level of acuity or functioning before surgery. Investigation of this provided further information for the interpretation of the overall impact of surgery on visual function, allowing inferences for routine clinical practice to be drawn.. This concept has not been used before to examine the impact of cataract surgery on visual function. Pre-operative visual function was identified as an important confounder for the extent of *change* after surgery. The findings suggested that for a given level of pre-operative visual function, the better the pre-operative visual acuity in the better eye, then on average the greater the gain in visual function after surgery. The relationship with change (gain) in better eye visual acuity remained unchanged.

Given the wide variability in visual function scores before surgery for any level of visual acuity, and the important effect of age on pre-operative visual acuity and function, the findings suggested that for a given level of function before surgery, more benefit (in terms of visual function) was gained post-operatively if cataract extraction was performed on the affected eye before visual acuity in the better eye was compromised. By identifying the importance of pre-operative *better* eye acuity and visual function on outcome, insight and information was provided regarding the timing of surgery to achieve most benefit in terms of visual function. This would not have been evident from clinical assessment of outcome by surgery eye visual acuity alone.

3. FUTURE HEALTH SERVICES RESEARCH

Finally, by identifying the current uses, limitations and contributions of the methods used to measure impairment (visual acuity), disability (visual function) and handicap (quality of life) for the assessment of the outcome of cataract surgery, the findings have informed their use in health services research :

i. **For international comparisons** of impairment, disability and handicap experienced by different populations of cataract patients and the outcomes of surgery in different health care settings. The patient perceived measures for disability and handicap used in this thesis were comparable to a similar study conducted in the United States, with the intention that comparative analyses will be undertaken now that both studies have been completed. The findings have provided information on their use and interpretation in the proposed comparative analyses.

ii. **To evaluate the impact of change in routine surgical practice.**

- For the assessment of alternative methods of delivering a service, such as in-patient versus day care

- For the assessment of new technologies and developments in intraocular lens design such as foldable lenses facilitating small incision surgery, and bifocal lenses

- For the assessment of alternative surgical techniques for cataract extraction. Visual function (VF-14) is already being used as an outcome measure in a randomised controlled trial of alternative surgical techniques for cataract extraction as a result of the work carried out in this thesis.

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APPENDIX A

NATIONAL CATARACT SURGERY STUDY

Appendix A1 - Information letter
Specimen forms with instructions for completion
Clinical Data Collection Forms
Consultant Data Collection Form

Appendix A2 - Poisson Logistic Regression Model :
Risk Factors for Poor Clinical Outcome - Visual Acuity

Appendix A3 - Poisson Logistic Regression Model :
Risk Factors for Poor Clinical Outcome - Complications

Appendix A1

Information letter

Specimen forms with instructions for completion

Clinical Data Collection Forms

Consultant Data Collection Form

COLLEGE OF OPHTHALMOLOGISTS

BRAMBER COURT, 2 BRAMBER ROAD, LONDON W14 9PQ

TELEPHONE: 071-385 6281 FACSIMILE: 071-381 1799

November 1990

THE NATIONAL CATARACT SURGERY SURVEY

I am pleased to be able to inform you that the survey week is:

WEEK 48 : MONDAY 26 - FRIDAY 30 NOVEMBER 1990.

Please find enclosed -

* **10 sets of patient survey forms**
  Each set consists of Part 1 and Part 2 per patient, [Forms COAU/001 and COAU/002 respectively.

  These are specifically for adult patients admitted under your care for surgery for age related cataract, during the survey week.

  Each set of forms is specially coded for patients of each participating Consultant. If we have not sent you sufficient, please contact -

  Miss N.Mahmood
  Audit Secretary
  College of Ophthalmologists
  Bramber Court, 2 Bramber Rd,
  London W14 9PQ

  Tel: 071 - 385 - 6281

* **Part 3 - Routine Hospital Data per Consultant.**
  [Form COAU/003]

  This information relates to *each Consultant* and may be obtained from your Hospital Management Information Department.

* **Specimen survey form with a guide to form completion.**

PTO

Once completed *Part 1 and Part 3* should be returned to the College at your *earliest convenience*, but preferably by

Monday 10 December 1990.

Part 2 should be returned to the College when completed at 3 months post-operatively.

Thank you for your cooperation and participation in the survey.

Yours sincerely,

Ms P Courtney MSc FRCS FCOphth
Audit Fellow

COLLEGE OF OPHTHALMOLOGISTS

NATIONAL CATARACT SURGERY SURVEY

NOTES ON SURVEY FORM COMPLETION

***PART 1**: Pre- and Peri-Operative Data*

This data should be obtained for all adult patients admitted for surgery for age related cataract during the survey week:

Monday 26 - Friday 30 November 1990.

It includes pre-operative and peri-operative data on each patient in the survey. This data should be collected during the admission episode for surgery and should be returned as soon as it is completed to the College of Ophthalmologists by Monday 10 December 1990.

PERSONAL DATA.

Ethnic Group - classify as apparent to the Ophthalmologist:

Caucasian	-	European origin
Asian	-	Indian sub-continent origin
Afro-Caribbean	-	African or Caribbean origin
Oriental	-	Far Eastern, Chinese, Japanese origin
Other	-	mixed origin or not include in above.

Occupation

Employed - if still in active employment (full or part-time)

Unemployed - if not in employment at time of admission but has previous history of employment

Retired - retired from full-time or part-time work

Housewife

PRE-OPERATIVE.

<u>Referral source</u> -

GP - General Practitioner

OMP / Optician - referral *directly* to hospital

Other - another department in the hospital
e.g. Geriatric or Diabetic Clinic.

<u>Date of referral letter</u> -

This should refer to the date at which an Ophthalmic consult was requested for the patient (including referrals from "*other*" sources.

<u>Date of first OPD appt.</u> -

Date at which patient was <u>*first*</u> seen in the Ophthalmic Out-Patient Clinic from <u>*any*</u> referral source.

PERI-OPERATIVE.

<u>Surgery Performed</u> -

No, medical reason - unfit for surgery
No, other reason - theatre closure,staff shortage,
operating list overbooked.

IMMEDIATE POST-OP.

This section relates to the <u>*first*</u> post-operative examination for both in-patients and day-cases.

For day-cases this would be the morning after surgery when these patients are requested to attend for their "first day" post-operative examination.

AT DISCHARGE.

For In-Patients - this section refers to the date that the patient is discharged from hospital after surgery.

For Day-Cases - this section refers to the day after surgery when these patients are requested to attend for their "first day" post-operative examination.

***PART 2*: Post-Operative Data**

This *post-operative data* should be obtained prospectively for all patients who have been included in the survey *and* have had Part 1 completed.

1ST POST-OP OPD VISIT.

This relates to data at the *first* post-operative visit in the Out-Patient Clinic.

3 MONTH POST-OP OPD VISIT.

This refers to post-operative data on patients *3 months after their operation*. It relates to data available on the patient at that time.

Once completed the survey forms should be returned to the College of Ophthalmologists at your earliest convenience.

***PART 3*: Routine Hospital Data per Consultant**

This information may be obtained from the Hospital Management Information Department.

(If this is not possible it may be obtained from Theatre Registers and the Out-Patient Appointments Diary).

If possible it should be completed and returned to the College with PART 1 by Monday 10 December 1990.

COAQ/001

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Pre and Peri-Operative Data for Cataract Operations in Adults

PART 1:

CENTRE ID: 0 0 7 9 4

CONSULT ID: 0 a 9 9 1

PATIENT ID: 0 0 c 0 6

PERSONAL DATA (Please circle)

HOSPITAL NUMBER: 0 3 9 6 5 1 7 0

Sex: M (F)

Date of Birth: 2 / 2 /1920

Ethnic Group:
(1 = Caucasian)
2 = Asian
3 = Afro-Caribbean
4 = Oriental
5 = Other
6 = Not recorded

Occupation:
1 = Employed
2 = Unemployed
3 = Retired
(4 = Housewife)
5 = Not known

PRE-OPERATIVE (Please circle)

Referral source:
(1 = GP)
2 = OMP/Optician
3 = Other
4 = Not known

	Day	Month	Year
Date referral letter:	8	8	1988
Date first OPD appt:	8	2	1989
Date listed for surgery:	10	4	1990
Date admission for surgery:	26	11	1990

Type of admission: (In-patient) Day case

EYE: Right (Left) (1ST) 2ND

Biometry: (Yes) No

SURGEON

VISUAL ACUITY (Please insert code)

	RIGHT	LEFT
At 1st OPD appointment:		
With correction:	3	4
Best corrected/Pin-hole:	2	4
Date listed for surgery:		
With correction:	3	6
Best corrected/Pin-hole:	3	6
Date admission for surgery:		
With correction:	3	8
Best corrected/Pin-hole:	3	8

CODE:

0 = Not recorded
1 = 6/6
2 = 6/9
3 = 6/12
4 = 6/18
5 = 6/24
6 = 6/36
7 = 6/60
8 = 3/60
9 = CF
10 = HM
11 = NPL

OCULAR PATHOLOGY ON ADMISSION

	RIGHT	LEFT
In order of severity:	1	9

If OTHER, please specify: _____

CODE:

0 = None

Age related maculopathy
1 = RPE changes/Drusen
2 = Disciform

Diabetic Retinopathy
3 = Background
4 = Proliferative
5 = Maculopathy

6 = **Glaucoma**
7 = **Amblyopia**
8 = Other
9 = Not known

PERI-OPERATIVE (Please circle)

Pre-op topical antibiotic: Yes (No)

Anaesthetic: Local (General)

Surgery performed: (1 = Yes) 2 = No, medical reasons 3 = No, other reason

Type of extraction: (1 = Extracapsular) 2 = Intracapsular 3 = Other

IOL: (1 = Post.Chamber) 2 = Ant. Chamber 3 = None

Peri-op complications: (0 = None) 1 = Capsule rupture 2 = Vitreous loss 3 = Choroidal haemorrhage 4 = Retro-bulbar haemorrhage 5 = Other

If OTHER, please specify: _____

_____

Intra-op antibiotic:

0 = None
1 = Topical
2 = Topical + steroid
3 = Subconjunctival
(4 = Subconj + steroid)
5 = Other
6 = Not recorded

Grade of Surgeon:

1 = Consultant
2 = SR
(3 = Registrar)
4 = SHO
5 = Other

If OTHER, specify _____

IMMEDIATE POST-OP (Please insert code)

Immediate post-op complications
In order of severity: [2] [1] [ ]

If OTHER, please specify: _____

_____

Additional ocular pathology detected after surgery in operated eye
In order of severity: [9] [ ] [ ]

If OTHER, please specify: _____

_____

Return to theatre for complications: Yes (No)

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Fibrinous uveitis
10 = Retinal detachment
11 = Other

CODE:

0 = None

Age related maculopathy
1 = RPE changes/Drusen
2 = Disciform

Diabetic Retinopathy
3 = Background
4 = Proliferative
5 = Maculopathy

6 = **Glaucoma**
7 = **Amblyopia**
8 = Other
9 = Not known

AT DISCHARGE (Please insert code)

Date discharged after surgery: 30 / 11 /1990

Visual acuity:	**RIGHT**	**LEFT**
With Correction:	0	0
Best corrected/Pin-hole:	0	7

CODE:

0 = Not recorded	6 = 6/36
1 = 6/6	7 = 6/60
2 = 6/9	8 = 3/60
3 = 6/12	9 = CF
4 = 6/18	10 = HM
5 = 6/24	11 = NPL

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Post-Operative Data for Cataract Operations in Adults

PART 2:

CENTRE ID: 0 0 7 9 4
CONSULT ID: 0 0 9 9 1
PATIENT ID: 0 0 0 0 6

PERSONAL DATA (Please circle)

Sex: M (F)

Date of Birth: 2 / 2 /1920

HOSPITAL NUMBER: 0 3 9 6 5 1 7 0

1ST POST-OP OPD VISIT (Please insert code)

Date 1st post-op OPD visit: 12 / 12 /1990

VISUAL ACUITY AT 1ST POST-OP OPD VISIT:

	RIGHT	LEFT
With Correction:	3	6
Best corrected/Pin-hole:	0	5

CODE:

0 = Not recorded
1 = 6/6
2 = 6/9
3 = 6/12
4 = 6/18
5 = 6/24
6 = 6/36
7 = 6/60
8 = 3/60
9 = CF
10 = HM
11 = NPL

Complications at 1st post-op OPD in operated eye
In order of severity:

0
[ ]
[ ]

If OTHER, please specify: _____

_____

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Fibrinous uveitis
10 = Retinal detachment
11 = Other

3 MONTHS POST-OP OPD VISIT (Please circle or insert code)

Status: (Discharged) Follow-up

Number of post-op visits at 3 months: 4

Date post-op medications discontinued: 6 / 2 /19 91

VISUAL ACUITY AT 3 MONTHS:

	RIGHT	LEFT
With Correction:	3	3
Best corrected/Pin-hole:	0	0

CODE:

0 = Not recorded
1 = 6/6
2 = 6/9
3 = 6/12
4 = 6/18
5 = 6/24
6 = 6/36
7 = 6/60
8 = 3/60
9 = CF
10 = HM
11 = NPL

3 MONTHS POST-OP OPD VISIT (Please circle or insert code)

Complications at 3 months in operated eye
In order of severity:

If OTHER, please specify: _____

_____

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Persistent uveitis
10 = Retinal detachment
11 = Cystoid macula oedema
12 = Soft Lens Matter
13 = Capsule Thickening
14 = Other

Suture removal: (Yes) No

Indication for suture removal:

(1 = Astigmatism)
2 = Loose suture
3 = Routine
4 = Other

If OTHER, specify

_____

Capsulotomy indicated: Yes (No)

Final refraction: (Yes) No

Final refraction performed at: (Hospital) Local Optician

Glasses dispensed: Yes No

Glasses dispensed at: Hospital Local Optician

Contact Lens dispensed: Yes No

Contact Lens dispensed at: Hospital Local Optician

ADDITIONAL NOTES (If indicated)

Please return Part 1 when completed and thereafter Part 2 to:-

Ms P Courtney FCOphth
Audit Unit
College of Ophthalmologists
Bramber Court
2 Bramber Road
London
W14 9PQ

THANK YOU FOR PARTICIPATING IN THIS SURVEY

COAU/003

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Routine Hospital Data
Per Consultant

PART 3:

CENTRE ID: 00794

CONSULT ID: 00991

	Study Week Week 48 (1990)	Weekly average Jul/Aug/Sep 1990	Weekly average Jan-Dec 1989
Number of Theatre sessions per week:	1	1	1
Number of OPD sessions per week:	2	2	2

	End of third quarter 30 Sep 1990	End of fourth quarter 31 Dec 1989
SURGICAL WAITING LIST FOR CATARACT		
Total number of patients on waiting list:	750	500
Number awaiting admission 6 months or less:	200	200
Number awaiting admission more than 6 months:	550	300
FIRST OUTPATIENT APPOINTMENT WAITING LIST		
Total number of patients on waiting list:	100	100
Average waiting time for routine appointment (in weeks):	18	18
Average waiting time for urgent appointment (in weeks):	6	6

	Jul 1990	Aug 1990	Sep 1990
Number of cataract operations per month in 3rd quarter 1990:	20	21	20
Total number of cataract operations JUL-SEP 1990:	61		
Total number of cataract operations JAN-DEC1989:	240		

Source of Information (Please Circle)

1 = Hospital Management Information

2 = Other

If other, please specify: _____

Please return Part 3 when completed to:-

Ms P Courtney FCOphth
Audit Unit
College of Ophthalmologists
Bramber Court
2 Bramber Road
London
W14 9PQ

THANK YOU FOR YOUR CO-OPERATION IN PROVIDING THIS INFORMATION

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Pre and Peri-Operative Data for Cataract Operations in Adults

PART 1:

CENTRE ID: ☐☐☐☐☐

CONSULT ID: ☐☐☐☐☐

PATIENT ID: ☐☐☐☐☐

PERSONAL DATA (Please circle)

HOSPITAL NUMBER: ☐☐☐☐☐☐☐☐

Sex: M F

Date of Birth: / /19

Ethnic Group:
1 = Caucasian
2 = Asian
3 = Afro-Caribbean
4 = Oriental
5 = Other
6 = Not recorded

Occupation:
1 = Employed
2 = Unemployed
3 = Retired
4 = Housewife
5 = Not known

PRE-OPERATIVE (Please circle)

Referral source:
1 = GP
2 = OMP/Optician
3 = Other
4 = Not known

	Day	Month	Year
Date referral letter:		/	/19
Date first OPD appt:		/	/19
Date listed for surgery:		/	/19
Date admission for surgery:		/	/19

Type of admission: In-patient Day case

EYE: Right Left 1ST 2ND

Biometry: Yes No

VISUAL ACUITY (Please insert code)

	RIGHT	LEFT
At 1st OPD appointment:		
With correction:	☐	☐
Best corrected/Pin-hole:	☐	☐
Date listed for surgery:		
With correction:	☐	☐
Best corrected/Pin-hole:	☐	☐
Date admission for surgery:		
With correction:	☐	☐
Best corrected/Pin-hole:	☐	☐

CODE:
0 = Not recorded
1 = 6/6
2 = 6/9
3 = 6/12
4 = 6/18
5 = 6/24
6 = 6/36
7 = 6/60
8 = 3/60
9 = CF
10 = HM
11 = NPL

OCULAR PATHOLOGY ON ADMISSION

	RIGHT	LEFT
In order of severity:	☐	☐
	☐	☐
	☐	☐

If OTHER, please specify: _____

CODE:
0 = None

Age related maculopathy
1 = RPE changes/Drusen
2 = Disciform

Diabetic Retinopathy
3 = Background
4 = Proliferative
5 = Maculopathy

6 = Glaucoma
7 = Amblyopia
8 = Other
9 = Not known

PERI-OPERATIVE (Please circle)

Pre-op topical antibiotic: Yes No

Anaesthetic: Local General

Surgery performed:
1 = Yes
2 = No, medical reasons
3 = No, other reason

Type of extraction:
1 = Extracapsular
2 = Intracapsular
3 = Other

IOL:
1 = Post.Chamber
2 = Ant. Chamber
3 = None

Peri-op complications:
0 = None
1 = Capsule rupture
2 = Vitreous loss
3 = Choroidal haemorrhage
4 = Retro-bulbar haemorrhage
5 = Other

If OTHER, please specify: _____

_____

Intra-op antibiotic:

0 = None
1 = Topical
2 = Topical + steroid
3 = Subconjunctival
4 = Subconj + steroid
5 = Other
6 = Not recorded

Grade of Surgeon:

1 = Consultant
2 = SR
3 = Registrar
4 = SHO
5 = Other

If OTHER, specify _____

IMMEDIATE POST-OP (Please insert code)

Immediate post-op complications
In order of severity:

☐
☐
☐

If OTHER, please specify: _____

_____

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Fibrinous uveitis
10 = Retinal detachment
11 = Other

Additional ocular pathology detected after surgery in operated eye
In order of severity:

☐
☐
☐

If OTHER, please specify: _____

_____

CODE:

0 = None

Age related maculopathy
1 = RPE changes/Drusen
2 = Disciform

Diabetic Retinopathy
3 = Background
4 = Proliferative
5 = Maculopathy

6 = Glaucoma
7 = Amblyopia
8 = Other
9 = Not known

Return to theatre for complications: Yes No

AT DISCHARGE (Please insert code)

Date discharged after surgery: / /19

Visual acuity:	**RIGHT**	**LEFT**
With Correction:	☐	☐
Best corrected/Pin-hole:	☐	☐

CODE:

0 = Not recorded	6 = 6/36
1 = 6/6	7 = 6/60
2 = 6/9	8 = 3/60
3 = 6/12	9 = CF
4 = 6/18	10 = HM
5 = 6/24	11 = NPL

COAU/002

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Post-Operative Data for Cataract Operations in Adults

PART 2:

CENTRE ID: ☐☐☐☐☐

CONSULT ID: ☐☐☐☐☐

PATIENT ID: ☐☐☐☐☐

PERSONAL DATA (Please circle)

Sex: M F

Date of Birth: / /19

HOSPITAL NUMBER: ☐☐☐☐☐☐☐☐

1ST POST-OP OPD VISIT (Please insert code)

Date 1st post-op OPD visit: / /19

VISUAL ACUITY AT 1ST POST-OP OPD VISIT:

	RIGHT	LEFT
With Correction:	☐	☐
Best corrected/Pin-hole:	☐	☐

CODE:

0 = Not recorded	6 = 6/36
1 = 6/6	7 = 6/60
2 = 6/9	8 = 3/60
3 = 6/12	9 = CF
4 = 6/18	10 = HM
5 = 6/24	11 = NPL

Complications at 1st post-op OPD in operated eye
In order of severity:

☐
☐
☐

If OTHER, please specify: _____

_____

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Fibrinous uveitis
10 = Retinal detachment
11 = Other

3 MONTHS POST-OP OPD VISIT (Please circle or insert code)

Status: Discharged Follow-up

Number of post-op visits at 3 months:

Date post-op medications discontinued: / /19

VISUAL ACUITY AT 3 MONTHS:

	RIGHT	LEFT
With Correction:	☐	☐
Best corrected/Pin-hole:	☐	☐

CODE:

0 = Not recorded	6 = 6/36
1 = 6/6	7 = 6/60
2 = 6/9	8 = 3/60
3 = 6/12	9 = CF
4 = 6/18	10 = HM
5 = 6/24	11 = NPL

3 MONTHS POST-OP OPD VISIT (Please circle or insert code)

Complications at 3 months in operated eye
In order of severity:

If OTHER, please specify: _____

_____

CODE:

0 = None
1 = Corneal oedema
2 = Raised IOP
3 = Wound leak
4 = Iris prolapse
5 = External infection
6 = Endophthalmitis
7 = Dislocated IOL
8 = Hyphaema
9 = Persistent uveitis
10 = Retinal detachment
11 = Cystoid macula oedema
12 = Soft Lens Matter
13 = Capsule Thickening
14 = Other

Suture removal: Yes No

Indication for suture removal:

1 = Astigmatism
2 = Loose suture
3 = Routine
4 = Other

If OTHER, specify

_____

Capsulotomy indicated: Yes No

Final refraction: Yes No

Final refraction performed at: Hospital Local Optician

Glasses dispensed: Yes No

Glasses dispensed at: Hospital Local Optician

Contact Lens dispensed: Yes No

Contact Lens dispensed at: Hospital Local Optician

ADDITIONAL NOTES (If indicated)

Please return Part 1 when completed and thereafter Part 2 to:-

Ms P Courtney FCOphth
Audit Unit
College of Ophthalmologists
Bramber Court
2 Bramber Road
London
W14 9PQ

THANK YOU FOR PARTICIPATING IN THIS SURVEY

COLLEGE OF OPHTHALMOLOGISTS

National Cataract Surgery Survey

Routine Hospital Data
Per Consultant

PART 3:

CENTRE ID: | | | | | |

CONSULT ID: | | | | | |

	Study Week Week 48 (1990)	Weekly average Jul/Aug/Sep 1990	Weekly average Jan-Dec 1989
Number of Theatre sessions per week:			
Number of OPD sessions per week:			

	End of third quarter 30 Sep 1990	End of fourth quarter 31 Dec 1989
SURGICAL WAITING LIST FOR CATARACT		
Total number of patients on waiting list:		
Number awaiting admission 6 months or less:		
Number awaiting admission more than 6 months:		
FIRST OUTPATIENT APPOINTMENT WAITING LIST		
Total number of patients on waiting list:		
Average waiting time for routine appointment (in weeks):		
Average waiting time for urgent appointment (in weeks):		

	Jul 1990	Aug 1990	Sep 1990
Number of cataract operations per month in 3rd quarter 1990:			
Total number of cataract operations JUL-SEP 1990:			
Total number of cataract operations JAN-DEC1989:			

Source of Information: (Please Circle)

1 = Hospital Management Information 2 = Other

If other, please specify: _____

Please return Part 3 when completed to:-

Ms P Courtney FCOphth
Audit Unit
College of Ophthalmologists
Bramber Court
2 Bramber Road
London
W14 9PQ

THANK YOU FOR YOUR CO-OPERATION IN PROVIDING THIS INFORMATION

Appendix A2

Poisson Logistic Regression Model :

Risk Factors for Poor Clinical Outcome - Visual Acuity

EGRET (R)

Epidemiological GRaphics, Estimation, and Testing package
ANALYSIS MODULE (PECAN), version 0.26.6 ; EPIXACT (R), version 0.03

Today's date: 3/18/96 at 11:51

Data file name: vaegl

23 variables and 959 observations

VARIABLES

1. CARD	2. REGION	3. TYPE	4. SIZE	5. SEXY
6. AGE2G	7. AGE3G	8. ADMTYPE	9. EYEorder	10. VAAD4G
11. OCPATHG	12. AN01	13. PERIG	14. Surgeon	15. VA3MG
16. C3M01	17. CAPSULOTOM	18. REF	19. GLASS	20. POOR1
21. DENOM	22. LWAIT	23. AWAIT		

VARIABLE	MISSING VALUE CODE(S)
SEXY	99.00000
ADMTYPE	99.00000
EYEorder	99.00000
AN01	99.00000
Surgeon	99.00000
REF	99.00000
LWAIT	99.00000
AWAIT	99.00000

ANALYSIS MODEL: Poisson regression

RISK TYPE: Relative risk (multiplicative)

RATE MULTIPLIER: -none-

OUTCOME SPECIFICATION: Outcome Variable Name: POOR1

{X}
{F}

FACTORED VARIABLES

VARIABLE	#LEVELS	BASE	VARIABLE	#LEVELS	BASE	VARIABLE	#LEVELS	BASE
REGION	19	1	TYPE	3	1	SIZE	4	1
SEXY	2	1	AGE2G	2	1	AGE3G	3	1
ADMTYPE	2	1	EYEorder	2	1	VAAD4G	4	1
OCPATHG	3	0	AN01	2	0	PERIG	4	0
Surgeon	5	1	VA3MG	4	1	C3M01	2	0
CAPSULOTOM	2	0	GLASS	2	0	AWAIT	3	1

{X}
{C}

Configuration

DATAFILE.....	vaegl	ANALYSIS....	PR
VARIABLES.....	23	RATE MULT...	-none-
OBSERVATIONS..	959	OUTCOME.....	POOR1

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-2.084	(.111)	<.001	.1244
OCPATHG='1'	.9134	(.172)	<.001	2.493
OCPATHG='2'	1.296	(.175)	<.001	3.653

DEVIANCE ON 956 DF = 560.145

OUTCOME= POOR1

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1244	.1001	.1547
OCPATHG='1'	2.493	1.779	3.492
OCPATHG='2'	3.653	2.594	5.145

Excluding unknown SEX

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-2.081	(.111)	<.001	.1248
OCPATHG='1'	.9103	(.172)	<.001	2.485
OCPATHG='2'	1.293	(.175)	<.001	3.642

DEVIANCE ON 954 DF = 559.647

OUTCOME= POOR1

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1248	.1004	.1552
OCPATHG='1'	2.485	1.774	3.481
OCPATHG='2'	3.642	2.586	5.129

Extend to include all others (excluding variables with missing values)

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
REGION='2'	.3712	1.439	1	.230
REGION='3'	.5864	4.338	1	.037
REGION='4'	-.1285	.1582	1	.691
REGION='5'	.3587E-01	.6053E-02	1	.938
REGION='6'	.5004E-01	.1610E-01	1	.899
REGION='7'	.3823	1.422	1	.233
REGION='8'	-.6421	3.965	1	.046
REGION='9'	-.7943E-01	.8210E-01	1	.774
REGION='10'	-.2565	.5012	1	.479
REGION='11'	-.2997	.8337	1	.361
REGION='12'	.2044	.5823	1	.445
REGION='13'	.1709	.2397	1	.624
REGION='14'	-.1270	.1396	1	.709
REGION='15'	.1939	.4163	1	.519
REGION='16'	-.4486	.7031	1	.402
REGION='17'	-.3271	1.420	1	.233
REGION='18'	-.1358	.2173	1	.641
REGION='19'	.1185	.1085	1	.742
REGION		15.68	18	.615
TYPE='2'	.7564E-01	.1528	1	.696
TYPE='3'	-.5306E-02	.1248E-02	1	.972
TYPE		.2128	2	.899
SIZE='2'	.1647	.8504	1	.356
SIZE='3'	-.1335	.6862	1	.407
SIZE='4'	-.9114E-01	.2901	1	.590
SIZE		1.589	3	.662
SEXY='2'	.3138	4.466	1	.035
AGE2G='2'	.4302	8.681	1	.003
VAAD4G='2'	-.4442	7.087	1	.008
VAAD4G='3'	-.9368E-01	.3249	1	.569
VAAD4G='4'	.4644	10.12	1	.001

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-2.625	(.149)	<.001	.7241E-01
OCPATHG='1'	.7128	(.174)	<.001	2.040
OCPATHG='2'	1.155	(.176)	<.001	3.176
C3M01='1'	.8515	(.149)	<.001	2.343
GLASS='1'	.6708	(.154)	<.001	1.956

DEVIANCE ON 952 DF = 502.591

LIKELIHOOD RATIO STATISTIC ON 1 DF = 20.093, p < .001

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
SIZE='2'	.1157	.4294	1	.512
SIZE='3'	-.1375	.7257	1	.394
SIZE='4'	-.5621E-01	.1077	1	.743
SIZE		1.184	3	.757
SEXY='2'	.3844	6.763	1	.009
AGE2G='2'	.3886	7.011	1	.008
VAAD4G='2'	-.3339	3.660	1	.056
VAAD4G='3'	-.8418E-01	.2626	1	.608
VAAD4G='4'	.3275	5.054	1	.025
VAAD4G		6.004	3	.111
PERIG='1'	-.8139E-01	.2783E-01	1	.868
PERIG='2'	.4736	1.895	1	.169
PERIG='3'	-.1489	.7463E-01	1	.785
PERIG		1.957	3	.581
REGION='2'	.3792	1.484	1	.223
REGION='3'	.6373	4.957	1	.026
REGION='4'	-.2467	.6443	1	.422
REGION='5'	.9532E-02	.4355E-03	1	.983
REGION='6'	.1534E-01	.1564E-02	1	.968
REGION='7'	.6132E-03	.4757E-05	1	.998
REGION='8'	-.6062	3.222	1	.073
REGION='9'	.8600E-02	.8877E-03	1	.976
REGION='10'	-.1492	.1498	1	.699
REGION='11'	-.2143	.3840	1	.535
REGION='12'	.2010	.5641	1	.453
REGION='13'	-.4087E-01	.1605E-01	1	.899
REGION='14'	.5097E-01	.1888E-01	1	.891
REGION='15'	.1509	.2592	1	.611
REGION='16'	-.3518	.3697	1	.543
REGION='17'	-.3445	1.601	1	.206
REGION='18'	-.2982E-01	.9432E-02	1	.923
REGION='19'	.1423E-01	.1700E-02	1	.967
REGION		12.82	18	.802
CAPSULOTOM='1'	.5615	5.214	1	.022
TYPE='2'	-.1859E-01	.9757E-02	1	.921
TYPE='3'	.5731E-01	.1465	1	.702
TYPE		.1738	2	.917

OVERALL SCORETEST ON 32 DF = 44.438, p = .071

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-2.849	(.176)	<.001	.5789E-01
OCPATHG='1'	.6841	(.174)	<.001	1.982
OCPATHG='2'	1.113	(.176)	<.001	3.044
C3M01='1'	.8468	(.148)	<.001	2.332
GLASS='1'	.6525	(.154)	<.001	1.920
AGE2G='2'	.4072	(.155)	.009	1.503

DEVIANCE ON 951 DF = 495.375

LIKELIHOOD RATIO STATISTIC ON 1 DF = 7.216, p = .007

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
SEXY='2'	.3379	5.066	1	.024
SIZE='2'	.7600E-01	.1876	1	.665
SIZE='3'	-.1341	.6878	1	.407
SIZE='4'	-.5042E-01	.8624E-01	1	.769
SIZE		1.085	3	.781
VAAD4G='2'	-.3726	4.630	1	.031
VAAD4G='3'	-.1078	.4335	1	.510
VAAD4G='4'	.3695	6.350	1	.012
VAAD4G		7.545	3	.056
PERIG='1'	-.9650E-01	.3963E-01	1	.842
PERIG='2'	.4205	1.542	1	.214
PERIG='3'	-.1327	.5808E-01	1	.810
PERIG		1.602	3	.659
REGION='2'	.4225	1.791	1	.181
REGION='3'	.7284	6.147	1	.013
REGION='4'	-.2266	.5329	1	.465
REGION='5'	.3465E-01	.5617E-02	1	.940
REGION='6'	-.3139E-01	.6814E-02	1	.934
REGION='7'	-.5735E-02	.4192E-03	1	.984
REGION='8'	-.6007	3.120	1	.077
REGION='9'	-.3414E-01	.1449E-01	1	.904
REGION='10'	-.1392	.1291	1	.719
REGION='11'	-.2640	.6145	1	.433
REGION='12'	.2736	.9885	1	.320
REGION='13'	-.6371E-01	.3970E-01	1	.842
REGION='14'	.2124E-01	.3362E-02	1	.954
REGION='15'	.1192	.1658	1	.684
REGION='16'	-.2618	.1792	1	.672
REGION='17'	-.3617	1.801	1	.180
REGION='18'	-.4596E-01	.2271E-01	1	.880
REGION='19'	.1320E-01	.1462E-02	1	.970
REGION		14.63	18	.687
CAPSULOTOM='1'	.6061	5.936	1	.015
TYPE='2'	-.2292E-01	.1486E-01	1	.903
TYPE='3'	.5386E-01	.1294	1	.719
TYPE		.1436	2	.931

OVERALL SCORETEST ON 31 DF = 37.533, p = .195

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-2.881	(.177)	<.001	.5609E-01
OCPATHG='1'	.7176	(.175)	<.001	2.049
OCPATHG='2'	1.106	(.176)	<.001	3.021
C3M01='1'	.6937	(.166)	<.001	2.001
GLASS='1'	.6570	(.154)	<.001	1.929
AGE2G='2'	.4247	(.155)	.006	1.529
CAPSULOTOM='1'	.5324	(.221)	.016	1.703

DEVIANCE ON 950 DF = 489.954

LIKELIHOOD RATIO STATISTIC ON 1 DF = 5.421, p = .020

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
SIZE='2'	.9131E-01	.2690	1	.604
SIZE='3'	-.1088	.4457	1	.504
SIZE='4'	-.9031E-01	.2802	1	.597
SIZE		1.096	3	.778
VAAD4G='2'	-.3771	4.753	1	.029
VAAD4G='3'	-.9670E-01	.3468	1	.556
VAAD4G='4'	.3610	6.045	1	.014
VAAD4G		7.371	3	.061
PERIG='1'	-.9821E-01	.4099E-01	1	.840
PERIG='2'	.3503	1.112	1	.292
PERIG='3'	-.2550	.2402	1	.624

PERIG		1.325	3	.723
REGION='2'	.4729	2.168	1	.141
REGION='3'	.7651	6.650	1	.010
REGION='4'	-.2917	.9183	1	.338
REGION='5'	.5502E-01	.1390E-01	1	.906
REGION='6'	-.4033E-01	.1138E-01	1	.915
REGION='7'	-.4745E-01	.2949E-01	1	.864
REGION='8'	-.6091	3.258	1	.071
REGION='9'	-.5986E-02	.4330E-03	1	.983
REGION='10'	-.1604	.1755	1	.675
REGION='11'	-.2594	.5890	1	.443
REGION='12'	.2577	.8863	1	.346
REGION='13'	-.9923E-01	.9958E-01	1	.752
REGION='14'	.5435E-01	.2132E-01	1	.884
REGION='15'	.1179	.1621	1	.687
REGION='16'	-.2362	.1412	1	.707
REGION='17'	-.3582	1.754	1	.185
REGION='18'	-.1743E-01	.3174E-02	1	.955
REGION='19'	.6027E-01	.2919E-01	1	.864
REGION		16.06	18	.589
SEXY='2'	.3384	5.073	1	.024
TYPE='2'	-.5846E-02	.9560E-03	1	.975
TYPE='3'	.6011E-01	.1616	1	.688
TYPE		.2297	2	.891

OVERALL SCORETEST ON 30 DF = 31.946, p = .370

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-3.097	(.205)	<.001	.4517E-01
OCPATHG='1'	.6929	(.175)	<.001	1.999
OCPATHG='2'	1.106	(.176)	<.001	3.021
C3M01='1'	.7046	(.166)	<.001	2.023
GLASS='1'	.6880	(.154)	<.001	1.990
AGE2G='2'	.3738	(.156)	.017	1.453
CAPSULOTOM='1'	.5325	(.221)	.016	1.703
SEXY='2'	.3551	(.158)	.025	1.426

DEVIANCE ON 949 DF = 484.724
LIKELIHOOD RATIO STATISTIC ON 1 DF = 5.230, p = .022

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
VAAD4G='2'	-.3810	4.869	1	.027
VAAD4G='3'	-.9954E-01	.3669	1	.545
VAAD4G='4'	.3729	6.434	1	.011
VAAD4G		7.728	3	.052
PERIG='1'	-.1561E-01	.9475E-03	1	.975
PERIG='2'	.2560	.6270	1	.428
PERIG='3'	-.2937	.3317	1	.565
PERIG		.9022	3	.825
REGION='2'	.4521	2.008	1	.156
REGION='3'	.7645	6.651	1	.010
REGION='4'	-.3638	1.498	1	.221
REGION='5'	.4217E-01	.8255E-02	1	.928
REGION='6'	-.8577E-01	.5359E-01	1	.817
REGION='7'	-.2482E-01	.7929E-02	1	.929
REGION='8'	-.6320	3.645	1	.056
REGION='9'	-.8995E-02	.9813E-03	1	.975
REGION='10'	-.1630	.1816	1	.670
REGION='11'	-.2946	.7868	1	.375
REGION='12'	.3103	1.234	1	.267
REGION='13'	-.5798E-01	.3268E-01	1	.857
REGION='14'	.9252E-01	.5973E-01	1	.807
REGION='15'	.9711E-01	.1117	1	.738
REGION='16'	-.2482	.1581	1	.691
REGION='17'	-.3288	1.420	1	.233

REGION='18'	-.4479E-01	.2147E-01	1	.884
REGION='19'	.1239	.1165	1	.733
REGION		17.17	18	.511
SIZE='2'	.7255E-01	.1716	1	.679
SIZE='3'	-.1078	.4368	1	.509
SIZE='4'	-.1229	.5246	1	.469
SIZE		1.557	3	.669
TYPE='2'	.1264E-01	.4413E-02	1	.947
TYPE='3'	.3600E-01	.5740E-01	1	.811
TYPE		.1260	2	.939

OVERALL SCORETEST ON 29 DF = 26.704, p = .588

End stepwise

Final Model -1-

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-3.097	(.205)	<.001	.4517E-01
OCPATHG='1'	.6929	(.175)	<.001	1.999
OCPATHG='2'	1.106	(.176)	<.001	3.021
C3M01='1'	.7046	(.166)	<.001	2.023
GLASS='1'	.6880	(.154)	<.001	1.990
AGE2G='2'	.3738	(.156)	.017	1.453
CAPSULOTOM='1'	.5325	(.221)	.016	1.703
SEXY='2'	.3551	(.158)	.025	1.426

DEVIANCE ON 949 DF = 484.724
LIKELIHOOD RATIO STATISTIC ON 1 DF = 5.230, p = .022

RESULTS [PR]

OUTCOME= POOR1

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.4517E-01	.3022E-01	.6753E-01
OCPATHG='1'	1.999	1.420	2.816
OCPATHG='2'	3.021	2.139	4.267
C3M01='1'	2.023	1.461	2.801
GLASS='1'	1.990	1.471	2.691
AGE2G='2'	1.453	1.070	1.975
CAPSULOTOM='1'	1.703	1.105	2.625
SEXY='2'	1.426	1.046	1.946

testing for interactions with ocpath

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
OCPATHG='1'.C3M01='1'	-.4642E-01	.2107E-01	1	.885
OCPATHG='2'.C3M01='1'	-.4309	1.777	1	.182
OCPATHG.C3M01		2.421	2	.298
OCPATHG='1'.GLASS='1'	-.3781	1.204	1	.273
OCPATHG='2'.GLASS='1'	-.2774E-01	.6682E-02	1	.935
OCPATHG.GLASS		1.506	2	.471
OCPATHG='1'.CAPSULOTOM='1'	-.2519	.3011	1	.583
OCPATHG='2'.CAPSULOTOM='1'	-.7447	3.213	1	.073
OCPATHG.CAPSULOTOM		5.277	2	.071
OCPATHG='1'.SEXY='2'	-.9072E-01	.6661E-01	1	.796
OCPATHG='2'.SEXY='2'	-.1744	.2562	1	.613
OCPATHG.SEXY		.5027	2	.778
OCPATHG='1'.AGE2G='2'	.3813E-01	.1248E-01	1	.911
OCPATHG='2'.AGE2G='2'	-.2086	.3512	1	.553
OCPATHG.AGE2G		.3670	2	.832

OVERALL SCORETEST ON 10 DF = 7.690, p = .659

End stepwise - no significant interactions

Final Model -1-

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-3.097	(.205)	<.001	.4517E-01
OCPATHG='1'	.6929	(.175)	<.001	1.999
OCPATHG='2'	1.106	(.176)	<.001	3.021
C3M01='1'	.7046	(.166)	<.001	2.023
GLASS='1'	.6880	(.154)	<.001	1.990
AGE2G='2'	.3738	(.156)	.017	1.453
CAPSULOTOM='1'	.5325	(.221)	.016	1.703
SEXY='2'	.3551	(.158)	.025	1.426

DEVIANCE ON 949 DF = 484.724

LIKELIHOOD RATIO STATISTIC ON 1 DF = 5.230, p = .022

Restricted Model - using only all known values:

[Using 856 observations; 103 have missing values]

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-3.112	(.218)	<.001	.4450E-01
OCPATHG='1'	.7125	(.188)	<.001	2.039
OCPATHG='2'	1.119	(.193)	<.001	3.062
C3M01='1'	.7170	(.182)	<.001	2.048
GLASS='1'	.6960	(.165)	<.001	2.006
AGE2G='2'	.2518	(.167)	.132	1.286
CAPSULOTOM='1'	.5711	(.237)	.016	1.770
SEXY='2'	.4144	(.174)	.017	1.514

DEVIANCE ON 848 DF = 425.923

RESULTS [PR]

OUTCOME= POOR1

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.4450E-01	.2901E-01	.6826E-01
OCPATHG='1'	2.039	1.412	2.945
OCPATHG='2'	3.062	2.099	4.468
C3M01='1'	2.048	1.435	2.923
GLASS='1'	2.006	1.451	2.772
AGE2G='2'	1.286	.9273	1.784
CAPSULOTOM='1'	1.770	1.113	2.815
SEXY='2'	1.514	1.076	2.128

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
ADMTYPE='2'	-.1516	.2436	1	.622
AN01='1'	-.2985E-02	.3527E-03	1	.985
Surgeon='2'	.1732	.3722	1	.542
Surgeon='3'	-.1716	.7021	1	.402
Surgeon='4'	-.1499	.2573	1	.612
Surgeon='5'	.7531E-02	.6138E-03	1	.980
Surgeon		1.279	4	.865
AWAIT='2'	-.4679E-01	.6372E-01	1	.801
AWAIT='3'	-.2625	1.734	1	.188
AWAIT		2.120	2	.347

OVERALL SCORETEST ON 8 DF = 3.585, p = .893

End stepwise

RESULTS [PR]

OUTCOME= POOR1

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-3.112	(.218)	<.001	.4450E-01
OCPATHG='1'	.7125	(.188)	<.001	2.039
OCPATHG='2'	1.119	(.193)	<.001	3.062
C3M01='1'	.7170	(.182)	<.001	2.048
GLASS='1'	.6960	(.165)	<.001	2.006
AGE2G='2'	.2518	(.167)	.132	1.286
CAPSULOTOM='1'	.5711	(.237)	.016	1.770
SEXY='2'	.4144	(.174)	.017	1.514

DEVIANCE ON 848 DF = 425.923

Maximum number of reals used in dynamic memory: 27314 out of 40000

Appendix A3

Poisson Logistic Regression Model :

Risk Factors for Poor Clinical Outcome - Complications

EGRET (R)

Epidemiological GRaphics, Estimation, and Testing package
ANALYSIS MODULE (PECAN), version 0.26.6 ; EPIXACT (R), version 0.03

THIS COPY LICENSED TO:
Dr. Parul Courtney
Audit Unit, College of Ophthalmologists
Bramber Court, 2 Bramber Road, London W14 9PQ, United Kingdom

Today's date: 3/24/96 at 20:52

Data file name: c:\concas\vaeg2

23 variables and 959 observations

VARIABLES

1. CARD	2. REGION	3. TYPE	4. SIZE	5. SEXY
6. AGE2G	7. AGE3G	8. ADMTYPE	9. EYEorder	10. VAAD4G
11. OCPATHG	12. AN01	13. PERIG	14. Surgeon	15. VA3MG
16. C3M01	17. CAPSULOTOM	18. REF	19. GLASS	20. POOR1
21. DENOM	22. LWAIT	23. AWAIT		

ANALYSIS MODEL: Poisson regression

RISK TYPE: Relative risk (multiplicative)

RATE MULTIPLIER: -none-

OUTCOME SPECIFICATION: Outcome Variable Name: C3M01

VARIABLE	MISSING VALUE CODE(S)
SEXY :	99.00000
ADMTYPE :	99.00000
EYEorder :	99.00000
AN01 :	99.00000
Surgeon :	99.00000
REF :	99.00000
LWAIT :	99.00000
AWAIT :	99.00000

FACTORED VARIABLES

VARIABLE	#LEVELS	BASE	VARIABLE	#LEVELS	BASE	VARIABLE	#LEVELS	BASE
REGION	19	1	TYPE	3	1	SIZE	4	1
SEXY	2	1	AGE2G	2	1	AGE3G	3	1
ADMTYPE	2	1	EYEorder	2	1	VAAD4G	4	1
OCPATHG	3	0	AN01	2	0	PERIG	4	0
Surgeon	5	1	VA3MG	4	1	CAPSULOTOM	2	0
REF	2	0	GLASS	2	0	LWAIT	3	1
AWAIT	3	1						

REGRESSION TERMS [PR]

a. %GM b. OCPATHG

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.844	(.985E-01)	<.001	.1582
OCPATHG='1'	.5045	(.174)	.004	1.656
OCPATHG='2'	.4492	(.207)	.030	1.567

DEVIANCE ON 956 DF = 594.745

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1582	.1304	.1919
OCPATHG='1'	1.656	1.179	2.327
OCPATHG='2'	1.567	1.043	2.353

Excluding all records with missing values for SEX :

NO OBSERVATIONS WITH MISSING VALUES IN ANY OF THE FOLLOWING VARIABLES WILL BE USED

A. SEXY

[Using 957 obs; 2 have missing values in key or use variables]

REGRESSION TERMS [PR]

a. %GM b. OCPATHG

[Using 957 observations; 2 have missing values]

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.841	(.985E-01)	<.001	.1587
OCPATHG='1'	.5014	(.174)	.004	1.651
OCPATHG='2'	.4461	(.207)	.032	1.562

DEVIANCE ON 954 DF = 594.111

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1587	.1308	.1925
OCPATHG='1'	1.651	1.175	2.320
OCPATHG='2'	1.562	1.040	2.346

Extend model to include all other variables (excluding those with missing values) :

REGRESSION TERMS [PR]

a. %GM b. OCPATHG c. REGION
d. TYPE e. SIZE f. SEXY
g. AGE2G

RESULTS [PR]

EXTENSION	PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
REGION='2'		-.4367	1.825	1	.177
REGION='3'		.2976	1.092	1	.296
REGION='4'		.5446	2.405	1	.121
REGION='5'		.4645	1.012	1	.314
REGION='6'		-.2574	.4227	1	.516
REGION='7'		1.013	9.415	1	.002
REGION='8'		-.3801	1.282	1	.258
REGION='9'		-.3877E-01	.1876E-01	1	.891
REGION='10'		-.1583	.1702	1	.680
REGION='11'		-.1241	.1327	1	.716
REGION='12'		-.9041E-01	.1067	1	.744
REGION='13'		.4128E-01	.1254E-01	1	.911
REGION='14'		-.4540	1.722	1	.189
REGION='15'		.6588E-01	.4584E-01	1	.830
REGION='16'		-.4661	.7815	1	.377
REGION='17'		.2024	.5107	1	.475
REGION='18'		-.4346	2.083	1	.149
REGION='19'		.3990	1.210	1	.271
REGION			23.74	18	.164
TYPE='2'		.3053	2.354	1	.125
TYPE='3'		-.3146	4.162	1	.041
TYPE			4.333	2	.115
SIZE='2'		.2618E-01	.1969E-01	1	.888
SIZE='3'		-.5343E-01	.1033	1	.748
SIZE='4'		-.1415	.6600	1	.417
SIZE			1.253	3	.740
SEXY='2'		-.1087E-01	.5054E-02	1	.943
AGE2G='2'		.1304	.7547	1	.385

OVERALL SCORETEST ON 25 DF = 27.305, p = .341

End stepwise

Final Model -1- :

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.841	(.985E-01)	<.001	.1587
OCPATHG='1'	.5014	(.174)	.004	1.651
OCPATHG='2'	.4461	(.207)	.032	1.562

DEVIANCE ON 954 DF = 594.111

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1587	.1308	.1925
OCPATHG='1'	1.651	1.175	2.320
OCPATHG='2'	1.562	1.040	2.346

testing for interactions between ocular pathology, age and sex :

REGRESSION TERMS [PR]

a. %GM
b. OCPATHG
c. OCPATHG.SEXY
d. OCPATHG.AGE2G

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.841	(.985E-01)	<.001	.1587
OCPATHG='1'	.7397	(.284)	.009	2.095
OCPATHG='2'	.3558	(.392)	.364	1.427
OCPATHG='1'.SEXY='2'	-.2432	(.298)	.415	.7841
OCPATHG='2'.SEXY='2'	.9051E-01	(.379)	.811	1.095
OCPATHG='1'.AGE2G='2'	-.1379	(.294)	.639	.8712
OCPATHG='2'.AGE2G='2'	.5414E-01	(.379)	.886	1.056

DEVIANCE ON 950 DF = 592.990
LIKELIHOOD RATIO STATISTIC ON 4 DF = 1.120, p = .891

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1587	.1308	.1925
OCPATHG='1'	2.095	1.202	3.653
OCPATHG='2'	1.427	.6616	3.079
OCPATHG='1'.SEXY='2'	.7841	.4370	1.407
OCPATHG='2'.SEXY='2'	1.095	.5207	2.302
OCPATHG='1'.AGE2G='2'	.8712	.4899	1.549
OCPATHG='2'.AGE2G='2'	1.056	.5021	2.220

Restricted Model - to include all variables of interest, but using only all known values :

NO OBSERVATIONS WITH MISSING VALUES IN ANY OF THE FOLLOWING VARIABLES WILL BE USED

A. SEXY B. ADMTYPE C. AN01 D. Surgeon

[Using 869 obs; 90 have missing values in key or use variables]

REGRESSION TERMS [PR]

a. %GM b. OCPATHG

[Using 869 observations; 90 have missing values]

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.875	(.105)	<.001	.1533
OCPATHG='1'	.5448	(.181)	.003	1.724
OCPATHG='2'	.5253	(.216)	.015	1.691

DEVIANCE ON 866 DF = 535.533

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1533	.1247	.1885
OCPATHG='1'	1.724	1.209	2.460
OCPATHG='2'	1.691	1.106	2.584

Extending the model to include the other variables of interest :

REGRESSION TERMS [PR]

a. %GM	b. OCPATHG	c. REGION
d. TYPE	e. SIZE	f. SEXY
g. AGE2G	h. ADMTYPE	i. AN01
j. Surgeon		

RESULTS [PR]

EXTENSION PARAMETER/TERM	BETA STEP	SCORETEST	DF	P-VALUE
REGION='2'	-.3277	.8774	1	.349
REGION='3'	.7204E-01	.5425E-01	1	.816
REGION='4'	.5016	1.926	1	.165
REGION='5'	.3592	.5579	1	.455
REGION='6'	-.1467	.1206	1	.728
REGION='7'	1.028	8.612	1	.003
REGION='8'	-.5705	2.669	1	.102
REGION='9'	-.9327E-01	.9700E-01	1	.755
REGION='10'	-.5341E-01	.1732E-01	1	.895
REGION='11'	-.1733	.2384	1	.625
REGION='12'	-.9651E-01	.1126	1	.737
REGION='13'	.2178	.3004	1	.584
REGION='14'	-.4266	1.447	1	.229
REGION='15'	.5925E-02	.3565E-03	1	.985
REGION='16'	-.4578	.7401	1	.390
REGION='17'	.2123	.4891	1	.484
REGION='18'	-.3441	1.145	1	.285
REGION='19'	.4190	1.313	1	.252
REGION		19.74	18	.348
TYPE='2'	.3891	3.513	1	.061
TYPE='3'	-.3345	4.271	1	.039
TYPE		4.932	2	.085
SIZE='2'	.5748E-02	.8387E-03	1	.977
SIZE='3'	-.8929E-01	.2597	1	.610
SIZE='4'	-.1170	.4071	1	.523
SIZE		1.319	3	.725
SEXY='2'	.1732E-02	.1158E-03	1	.991
AGE2G='2'	.1988	1.577	1	.209
ADMTYPE='2'	.3047	.8159	1	.366
AN01='1'	-.1824E-01	.1329E-01	1	.908
Surgeon='2'	.1094	.1755	1	.675
Surgeon='3'	-.9558E-01	.2193	1	.640
Surgeon='4'	-.2303	.6158	1	.433
Surgeon='5'	-.3040E-01	.9613E-02	1	.922
Surgeon		1.054	4	.902

OVERALL SCORETEST ON 31 DF = 28.303, p = .605

End stepwise

Final Restricted Model 2- :

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.875	(.105)	<.001	.1533
OCPATHG='1'	.5448	(.181)	.003	1.724
OCPATHG='2'	.5253	(.216)	.015	1.691

DEVIANCE ON 866 DF = 535.533

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1533	.1247	.1885
OCPATHG='1'	1.724	1.209	2.460
OCPATHG='2'	1.691	1.106	2.584

Adding age, sex, and surgeon to final restricted model -2- :

REGRESSION TERMS [PR]

a. %GM b. OCPATHG c. SEXY
d. AGE2G e. Surgeon

RESULTS [PR]

OUTCOME= C3M01

TERM	COEFFICIENT	STD ERROR	P-VALUE	RATE RATIO
%GM	-1.934	(.174)	<.001	.1446
OCPATHG='1'	.5244	(.183)	.004	1.689
OCPATHG='2'	.4956	(.219)	.023	1.641
SEXY='2'	-.2280E-01	(.163)	.889	.9775
AGE2G='2'	.2100	(.163)	.197	1.234
Surgeon='2'	.5593E-01	(.257)	.828	1.058
Surgeon='3'	-.1206	(.217)	.579	.8864
Surgeon='4'	-.2848	(.333)	.393	.7522
Surgeon='5'	-.7714E-01	(.320)	.810	.9258

DEVIANCE ON 860 DF = 532.750
LIKELIHOOD RATIO STATISTIC ON 6 DF = 2.783, p = .836

RESULTS [PR]

OUTCOME= C3M01

TERM	RATE RATIO	95% CONFIDENCE BOUNDS	
%GM	.1446	.1028	.2034
OCPATHG='1'	1.689	1.179	2.420
OCPATHG='2'	1.641	1.070	2.519
SEXY='2'	.9775	.7100	1.346
AGE2G='2'	1.234	.8965	1.698
Surgeon='2'	1.058	.6387	1.751
Surgeon='3'	.8864	.5788	1.357
Surgeon='4'	.7522	.3914	1.446
Surgeon='5'	.9258	.4941	1.735

Maximum number of reals used in dynamic memory: 26881 out of 40000

APPENDIX B

THE CATARACT OUTCOME STUDY : METHODS

Appendix B1 - Patient information letter

Appendix B2 - Clinical data collection booklet

Appendix B3 - Patient interview booklet

Appendix B1

Patient information letter

THE COLLEGE OF OPHTHALMOLOGISTS

and

THE WELLHOUSE TRUST

THE CATARACT OUTCOME STUDY

This study is being conducted in the hospital that you are having your cataract operation. It is being conducted with the College of Ophthalmologists and has the support of the Department of Health and your Eye Consultant.

The study is trying to reach a better understanding of the problems people with cataracts experience in carrying out their daily activities and how the operation changes this. We already have a lot of information on how surgery effects the eye, but there is a great need to advance our knowledge of the patient's experience of the process.

Participation is totally voluntary. It will involve **3** interviews of about 45-60 minutes each. The first will be conducted before your operation, the second at four months afterwards and the third interview will be conducted one year after the operation. If you have an operation on the second eye you may be asked to continue your participation in the study and have two further interviews. These interviews will take place in the hospital and will be conducted by a trained interviewer who is a part of the investigating team.

In the interview we will ask you questions about your vision, your general health, your everyday activities and how they are affected by your cataract, as well as the care you are receiving for your cataract. You may of course leave out an answer to any of the questions or even leave the study itself and it will not affect the timing of your operation or the post-operative follow-up in any way at all.

P.T.O.

Your answers will be confidential and will not be seen by your doctor or anyone else involved in your medical care. The information collected will go to the College of Ophthalmologists where only the study investigators will have access to it. At the end of the study, your name will be removed from all the interviews.

We hope that this study will give us a better understanding of how we are caring for our cataract patients and how we can improve on it.

If you would like to take part in the study, we would hope to interview you when you come in to the hospital for your pre-operative assessment. However if you particularly want to be interviewed at your home then we would do our best to arrange this for you.

A member of the Cataract Outcome Study Team will contact you by telephone within 2 days of the time we would have expected you to have received this letter to ask you if you would like to take part in this study.

We hope that you will consider taking part in this study. If you have any questions about it you may contact:

Don Fraser
The Cataract Outcomes Project Worker
Eye Department
Edgware General Hospital
Burnt Oak Broadway
Middlesex HA8 OAD

Tel : 081 - 200 - 1555 extension 3592 or 3419.

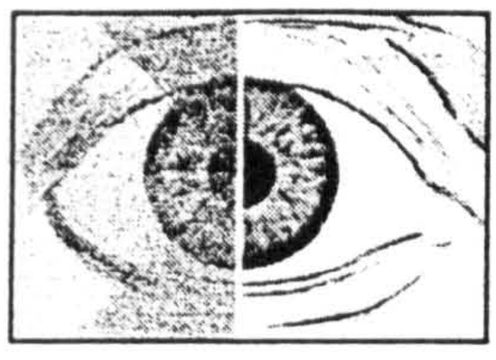
Appendix B2

Clinical data collection booklet

Patient ID

5	2	3	8

THE CATARACT OUTCOME STUDY



THE WELLHOUSE TRUST

CLINICAL DATA FORMS

Patient Name: _____

Hospital Number: _____

Consultant: _____

Patient ID

5	2	3	8

BASELINE
CLINICAL DATA FORM

Patient Name: _____
Patient Hospital No: _____
Consultant: _____
Hospital: _____

This form is to be used to provide **preoperative** clinical data about the patient named above who is scheduled for cataract surgery. It should be completed during the **admission episode**.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed; please return to :

Ms P. Courtney
College of Ophthalmologists
17 Cornwall Terrace
Regents Park
London NW1 4QW

Patient ID

5	2	3	8

Cataract Outcome Study

Baseline Clinical Data Form - Page 1 of 4

PERSONAL DATA

Sex: M ☐ F ☐ Date of Birth: / /19

Ethnic Group:(*Please circle*)

1 = Caucasian
2 = Asian
3 = Afro-Caribbean
4 = Oriental
5 = Other
6 = Not recorded

PRE-OPERATIVE (*Please circle*)

			Day	Month	Year
Referral source:	1 = GP	Date of referral letter:		/	/19
	2 = OMP/Optician directly	Date first OPD appt:		/	/19
	3 = OMP/Optician via GP	Date listed for surgery:		/	/19
	4 = Other	Date admission for surgery:		/	/19
	5 = Not known				

Type of admission: ☐ In-patient ☐ Day case Eye order: ☐1st ☐2nd

---

1. OPHTHALMIC HISTORY

Does the patient have any eye disease other than cataract? ☐ YES ☐ NO (GO TO Q2)

IF YES: Does the patient have any of the following? *(Please tick YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Amblyopia	☐	☐	Previous retinal detachment
☐	☐	Chronic external disease (e.g.; blepharoconjunctivitis)	☐	☐	Diabetic retinopathy (any degree)
☐	☐	Dry eye syndrome	☐	☐	Diabetic retinopathy with past laser treatment
☐	☐	"Fuchs" Dystrophy	☐	☐	Glaucoma or ocular hypertension (any degree)
☐	☐	Chronic uveitis or keratitis	☐	☐	Glaucoma with central field loss or previous laser or filtration surgery
☐	☐	Visually impairing age-related macular degeneration (Age Related Maculopathy)	☐	☐	Other optic nerve disease
			☐	☐	History of prior intraocular surgery

2. MEDICAL HISTORY AT BASELINE

Does the patient have any known medical conditions? ☐ YES ☐ NO (GO TO Q3)

IF YES: Does the patient have any of the following? *(Please tick YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Type-I diabetes (juvenile or ketoacidosis prone)	☐	☐	Chronic renal disease
☐	☐	Type-II diabetes (adult; not ketoacidosis prone)	☐	☐	Neoplasm
☐	☐	Hypertension	☐	☐	Chronic steroid therapy
☐	☐	Angina	☐	☐	Inflammatory bowel disease
☐	☐	Past myocardial infarction	☐	☐	Rheumatoid or collagen vascular disease
☐	☐	Past stroke	☐	☐	Deafness
☐	☐	Asthma; COPD; or bronchitis	☐	☐	Altered mental status

3. BEST CORRECTED VISUAL ACUITY

(Choices: 6/6, 6/9, 6/12, 6/18, 6/24, 6/36, 6/60, 3/60; CF; HM; PL; NPL)

At 1st OPD appointment:	6/I_I_I	6/I_I_I
Date listed for surgery:	6/I_I_I	6/I_I_I
Date of pre-op assessment / or admission:	6/I_I_I	6/I_I_I

4. REFRACTION

RIGHT EYE +/- I_I·I_I_I+I_I·I_I_IxI_I_I_I
CIRCLE SPHERE CYL AXIS

LEFT EYE +/- I_I·I_I_I+I_I·I_I_IxI_I_I_I
CIRCLE SPHERE CYL AXIS

☐ Not Known

Patient ID

Cataract Outcome Study

Baseline Clinical Data Form - Page 2 of 4

5. **KERATOMETRY IN DIOPTERS** (in operated eye) |__|__|·|__|D @|__|__|__|°;|__|__|·|__|__|D @|__|__|__|°

6. **AXIAL LENGTH** (in operated eye) |__|__|·|__|__|

7. **INTRAOCULAR PRESSURE** (applanation) **RIGHT** |__|__|mm **LEFT** |__|__|mm

8. **PUPILS**

RIGHT	LEFT	
☐	☐	Normally reactive
☐	☐	Afferent defect
☐	☐	Cannot assess

9. **CONJUNCTIVA; CORNEA; AND SCLERA** *(Tick one for each eye)*

RIGHT	LEFT		
☐	☐	Normal	
☐	☐	Abnormal (*if abnormal*) ⟶	**RIGHT LEFT** *(Tick all that apply)*
☐	☐	Cannot assess	☐ ☐ Prior filtering surgery
			☐ ☐ Gutatta (exceeding expected for age)
			☐ ☐ Oedema
			☐ ☐ Corneal scar reducing vision
			☐ ☐ Graft
			☐ ☐ Other corneal pathology_____
			_____

10. **ANTERIOR CHAMBER FINDINGS** *(Tick one for each eye)*

RIGHT	LEFT		
☐	☐	Normal	
☐	☐	Abnormal (*if abnormal*) ⟶	**RIGHT LEFT** *(Tick all that apply)*
☐	☐	Cannot assess	☐ ☐ Active uveitis or iridocyclitis
			☐ ☐ Posterior synechiae
			☐ ☐ Vitreous in AC
			☐ ☐ Other AC findings

11. **LENS** *(Tick one for each eye)*

RIGHT	LEFT		
☐	☐	Normal	
☐	☐	Nuclear cataract	
☐	☐	Cortical cataract	
☐	☐	Posterior subcapsular cataract	
☐	☐	Mixed Cataract	
☐	☐	Other abnormality (indicate) ⟶	**RIGHT LEFT** *(Tick all that apply)*
☐	☐	Cannot assess	☐ ☐ Hypermature cataract
			☐ ☐ Congenital cataract
			☐ ☐ Secondary cataract
			☐ ☐ Lens dislocation or subluxation

12. **OPTIC NERVE** *(Tick one for each eye)*

RIGHT	LEFT		
☐	☐	Normal	
☐	☐	Abnormal (*if abnormal*) ⟶	**RIGHT LEFT** *(Tick all that apply)*
☐	☐	Cannot assess	☐ ☐ Glaucomatous atrophy (cupping)
			☐ ☐ Non-glaucomatous atrophy
			☐ ☐ Other optic nerve findings

Patient ID

5	2	3	8

Cataract Outcome Study

Baseline Clinical Data Form - Page 3 of 4

13. **MACULA** *(Tick one for each eye)*

RIGHT	LEFT	
☐	☐	Normal
☐	☐	Abnormal (*if abnormal*) →
☐	☐	Cannot assess

RIGHT	LEFT	(*Tick all that apply*)
☐	☐	Scattered drusen
☐	☐	Confluent drusen
☐	☐	Nongeographic (mottled)
☐	☐	Geographic atrophy
☐	☐	Neovascular change or membrane
☐	☐	Disciform scar or hemorrhage
☐	☐	Macular oedema
☐	☐	Macular hole/cyst
☐	☐	Other macular or RPE pathology

14 **RETINA** *(Tick one for each eye)*

RIGHT	LEFT	
☐	☐	Normal
☐	☐	Abnormal (*if abnormal*) →
☐	☐	Cannot assess

RIGHT	LEFT	(*Tick all that apply*)
☐	☐	Retinal detachment
☐	☐	Background diabetic retinopathy
☐	☐	Pre-proliferative retinopathy
☐	☐	Proliferative diabetic retinopathy
☐	☐	Panretinal photocoagulation (previous)
☐	☐	Vitreous haemorrhage
☐	☐	Branch retinal artery occlusion
☐	☐	Central retinal artery occlusion
☐	☐	Branch retinal vein occlusion
☐	☐	Central retinal vein occlusion
☐	☐	Retinal degen.(myopic;lattice;etc.)
☐	☐	Other retinal pathology

15. **EYE SCHEDULED FOR CATARACT SURGERY FIRST** (*Tick one*) ☐ **RIGHT** ☐ **LEFT**

16. **TYPE OF SURGERY PLANNED** (*Tick one*)

☐ Extracapsular (manual expression of nucleus)
☐ Intracapsular
☐ Extracapsular (phacoemulsification)
☐ Other_____

17. **IOL PLANNED** (*Tick one*)

☐ Posterior chamber standard
☐ Posterior chamber foldable
☐ Anterior chamber
☐ Other
☐ None

18. **RISK ASSESSMENT**

Is there increased risk in this patient of: (*Please tick YES or NO for each condition*)

YES	NO	
☐	☐	Chronic inflammation
☐	☐	Haemorrhage or hyphaema
☐	☐	Zonular or capsular rupture
☐	☐	Vitreous loss or vitrectomy
☐	☐	Retinal break/retinal detachment
☐	☐	Corneal oedema

YES	NO	
☐	☐	Cystoid macular oedema
☐	☐	Transient IOP increase
☐	☐	Transient hypotony
☐	☐	Sustained glaucoma
☐	☐	Sustained hypotony
☐	☐	Other

IF YES TO ANY OF THE ABOVE; EXPLAIN BELOW:

Patient ID

Cataract Outcome Study

Baseline Clinical Data Form - Page 4 of 4

19. **EXPECTED POSTOPERATIVE ACUITY IN OPERATED EYE** (Tick one)

- ☐ 6/6 - 6/12
- ☐ 6/18 - 6/24
- ☐ 6/36 - 6/60
- ☐ 3/60 or worse

IF 6/12 OR WORSE; EXPLAIN BELOW:

_____

_____

_____

_____

20. **GRADE OF SURGEON MAKING PRE-OP ASSESSMENT:** _____
(Consultant, SR, Reg, SHO, Other)

21. **DATE OF PRE-OPERATIVE ASSESSMENT** / / **19**
DAY MONTH YEAR

22. DATE LAST SEEN IN OPD CLINIC / / 19
DAY MONTH YEAR

THANK YOU FOR COMPLETING THIS FORM

Patient ID

5	2	3	8

Thank you for completing this form

Cataract Outcome Study

PERIOPERATIVE CLINICAL DATA FORM

Patient Name: _____

Patient Hospital No: _____

Consultant: _____

Hospital: _____

This form should be completed during the patients' admission episode, **preferably within 48 hours** following surgery.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK"

When completed; please return to:

Ms P. Courtney
College of Ophthalmologists
17 Cornwall Terrace
Regents Park
London NW1 4QW

Patient ID

5	2	3	8

Cataract Outcome Study

Perioperative Clinical Data Form - Page 1 of 2

SURGICAL APPROACH

1. **OPERATED EYE** (DATE OF SURGERY: |__|__|·|__|__|·|__|__|__|) ☐ **RIGHT** ☐ **LEFT**
DAY MONTH YEAR

2. **TYPE OF CATARACT EXTRACTION** *(Tick one)*

☐ Extracapsular (manual expression of nucleus)
☐ Extracapsular (phacoemulsification)
☐ Converted (Phacoemulsification converted to standard extracapsular technique)
☐ Intracapsular

3. **TYPE OF ANAESTHESIA** *(Tick one)*

☐ General
☐ Retrobulbar block
☐ Peribulbar block

If retrobulbar or peribulbar: (Tick one in each box)

(Tick one)
☐ Patient monitored by anaesthetist
☐ Patient monitored by someone else *(Specify)*
_____

(Tick one)
☐ Block administered by surgeon
☐ Block administered by anaesthetist
☐ Block administered by someone else *(Specify)*
_____

4. **GRADE OF SURGEON PERFORMING SURGERY:** _____
(Consultant, SR, Reg, SHO, Other)

5. **INCISION LENGTH** ☐ Small ☐ Standard ☐ Long

6. **TYPE OF CAPSULOTOMY** *(Tick one)*

☐ Can opener with cystotome/needle
☐ Scissors capsulotomy
☐ Continuous tear capsulotomy

5a. **INCISION SITE**

☐ Corneal
☐ Scleral
☐ Limbal

7. **INTRAOCULAR LENS** *(Tick one)*

☐ Standard posterior chamber in bag
☐ Standard posterior chamber in sulcus
☐ Foldable posterior chamber
☐ Anterior chamber
☐ Planned suturing of posterior chamber lens
☐ Unplanned suturing of posterior chamber lens
☐ IOL planned but not implanted
☐ No IOL planned
☐ Multifocal

8. **TYPE OF IRIDECTOMY** *(Tick one)*

☐ Peripheral iridotomy
☐ Peripheral iridectomy
☐ Sector
☐ None

9. **INTRAOPERATIVE POSTERIOR CAPSULOTOMY?** *(Tick one)*

☐ Yes
☐ No

Patient ID

Cataract Outcome Study

Perioperative Clinical Data Form - Page 2 of 2

INTRAOPERATIVE AND POSTOPERATIVE COURSE

10. INTRAOPERATIVE EVENTS

Did the patient have any of the following? *(Please tick YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Globe perforation during anaesthesia	☐	☐	Posterior capsular or zonular rupture
☐	☐	Retrobulbar haemorrhage	☐	☐	Vitreous loss/anterior vitrectomy or aspiration
☐	☐	Other anaesthesia related complication	☐	☐	Loss of nuclear fragment into vitreous
☐	☐	Anterior chamber hemorrhage	☐	☐	Loss of IOL into vitreous
☐	☐	Iridodialysis; cyclodialysis or iris trauma	☐	☐	Choroidal haemorrhage
☐	☐	Persistent iris prolapse	☐	☐	Asymetric lens placement
☐	☐	Incomplete cortical clean up	☐	☐	Abnormality in wound closure
☐	☐	Residual posterior capsule opacity			

11. POSTOPERATIVE EVENTS (Within 48 hours following surgery)

Does the patient have any of the following? *(Please Tick YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Endophthalmitis	☐	☐	Cystoid macular oedema
☐	☐	Wound Leak or rupture	☐	☐	Retinal detachment
☐	☐	Hyphaema	☐	☐	Retinal tear or break (no detachment)
☐	☐	Posterior capsule opacification	☐	☐	Intraocular pressure greater than 30 mm Hg; pupillary block
☐	☐	IOL dislocation	☐	☐	Intraocular pressure greater than 30 mm Hg; non pupilary block
☐	☐	Retained lens material	☐	☐	Optic neuropathy
☐	☐	Inflammation greater than expected	☐	☐	Other complication (Specify)_____
☐	☐	Iris abnormalities (atrophy; etc.)			
☐	☐	Corneal oedema			

12. IS SURGERY PLANNED FOR SECOND EYE?

☐ No ☐ Yes. DATE if known ___/___/19___ ☐ Yes. date unknown

13. DATE OF SURGERY

/ / 19
DAY MONTH YEAR

IMPORTANT: IF CATARACT SURGERY IS SCHEDULED FOR THE SECOND EYE WITHIN 4 MONTHS OF THE FIRST SURGERY, PLEASE NOTIFY THE INTERVIEWER ASSIGNED TO YOUR HOSPITAL.

Thank you for completing this form

Patient ID

5	2	3	8

Cataract Outcome Study

4-MONTH FOLLOW UP CLINICAL DATA FORM

Patient Name: _____

Patient Hospital No: _____

Consultant: _____

Hospital: _____

This form should be completed **not later than 3 to 4 months** after surgery.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed; please return to :

Ms P. Courtney
College of Ophthalmologists
17 Cornwall Terrace
Regents Park
London NW1 4QW

Patient ID

5	2	3	8

Cataract Outcome Study

4 Months Follow Up Clinical Data Form - Page 1 of 2

OUTCOME OF CATARACT SURGERY
Day 0 - Day 120 (First 4 Months)

1. POSTOPERATIVE EVENTS *(Tick YES or NO)*

IF YES: *Give date*

YES	NO		DAY MONTH YEAR
☐	☐	Endophthalmitis	I_I_I·I_I_I·I_I_I
☐	☐	Wound Leak or rupture	I_I_I·I_I_I·I_I_I
☐	☐	Hyphaema	I_I_I·I_I_I·I_I_I
☐	☐	Retinal detachment	I_I_I·I_I_I·I_I_I
☐	☐	IOL dislocation	I_I_I·I_I_I·I_I_I
☐	☐	IOL removed or exchange	I_I_I·I_I_I·I_I_I
☐	☐	Retained lens material	I_I_I·I_I_I·I_I_I
☐	☐	Inflammation greater than expected	I_I_I·I_I_I·I_I_I
☐	☐	Iris abnormalities (synechiae; etc)	I_I_I·I_I_I·I_I_I
☐	☐	Corneal oedema greater than expected peripherally	I_I_I·I_I_I·I_I_I
☐	☐	Corneal oedema greater than expected centrally	I_I_I·I_I_I·I_I_I

YES	NO		DAY MONTH YEAR
☐	☐	Cystoid macular oedema	I_I_I·I_I_I·I_I_I
☐	☐	Posterior vitreous detachment	I_I_I·I_I_I·I_I_I
☐	☐	Posterior capsule opacification	I_I_I·I_I_I·I_I_I
☐	☐	Retinal scar or break (no detachment)	I_I_I·I_I_I·I_I_I
☐	☐	Intraocular pressure greater than 30 mmHg	I_I_I·I_I_I·I_I_I
☐	☐	Optic neuropathy	I_I_I·I_I_I·I_I_I
☐	☐	Other complication *(Specify)* _____ _____	I_I_I·I_I_I·I_I_I

2. SUTURES CUT?

☐ Yes ⟶ Number of visits at which suture(s) were cut:_____

☐ No

3. POSTERIOR CAPSULOTOMY PERFORMED?

☐ Yes (DATE: I_I_I·I_I_I·I_I_I) ⟶ If yes: *(Tick one)*
DAY MONTH YEAR

☐ Nd: YAG

☐ Needle/knife

☐ No

4. CATARACT SURGERY PLANNED IN SECOND EYE?

☐ No

☐ Yes; planned for (DATE: I_I_I·I_I_I·I_I_I) ☐ Yes; planned for date unknown

☐ Already performed (DATE: I_I_I·I_I_I·I_I_I)

5. BEST CORRECTED DISTANCE ACUITY (SNELLEN) **RIGHT** 6/I_I_I **LEFT** 6/I_I_I
(Choices: 6/6, 6/9, 6/12, 6/18, 6/24, 6/36, 6/60, 3/60; CF; HM; PL; NPL)

6. REFRACTION (In operated eye)

+/- I_I·I_I_I+I_I·I_I_I×I_I_I_I
CIRCLE SPHERE CYL AXIS

☐ Not Known

7. INTRAOCULAR PRESSURE (applanation) **RIGHT** I_I_Imm **LEFT** I_I_Imm

8. KERATOMETRY IN DIOPTERS (in operated eye) I_I_I·I_ID @I_I_I_I°; I_I_I·I_I_ID @I_I_I_I°

☐ Not Known

9. CORNEAL EXAMINATION (in operated eye) *(Tick all that apply)*

☐ Normal with secure wound and sutures
☐ Wound gape / leak
☐ Corneal oedema peripherally
☐ Corneal oedema centrally
☐ Broken sutures or protruding ends
☐ Descemet's folds
☐ Descemet's tear or detachment
☐ Other anormality:_____

Patient ID

Cataract Outcome Study

4 Months Follow Up Clinical Data Form - Page 2 of 2

10. **IRIS AND PUPIL** (In operated eye) (*Tick all that apply*)

- ☐ Normal with no iridectomy
- ☐ Normal with surgical iridectomy
- ☐ Non reactive pupil
- ☐ Ectatic or peaked pupil
- ☐ Iris atrophy (including phaco induced)
- ☐ Posterior synechia to capsule or IOL
- ☐ Anterior synechia
- ☐ Afferent pupillary defect
- ☐ Other abnormality:_____

11. **ANTERIOR CHAMBER FINDINGS** (In operated eye) (*Tick all that apply*)

- ☐ Normal
- ☐ Inflammation (cell and flare)
- ☐ Hypopyon
- ☐ Residual lens cortex
- ☐ Hyphaema
- ☐ Other abnormality_____

12. **LENS** (In operated eye) (*Tick all that apply*)

- ☐ Normally centered intraocular lens
- ☐ Edge of optic or dialling hole visible in undilated state
- ☐ Pupillary capture of IOL
- ☐ Posterior displacement of PC IOL optic or haptic
- ☐ Posterior displacement of anterior chamber IOL or haptic
- ☐ Residual lens cortex
- ☐ Other abnormality_____

13. **OPTIC NERVE** (In operated eye) (*Tick all that apply*)

- ☐ Normal
- ☐ Optic atrophy
- ☐ Optic nerve haemorrhage
- ☐ Glaucomatous atrophy
- ☐ Other abnormality_____

14. **MACULA** (In operated eye) *(Tick all that apply)*

- ☐ Normal
- ☐ Angiographic cystoid oedema
- ☐ Clinically significant cystoid oedema
- ☐ Age Related Maculopathy
- ☐ Macular cyst or hole
- ☐ Other abnormality_____

15. **RETINA** (*Tick all that apply*)

- ☐ Normal
- ☐ Retinal Detachment
- ☐ Retinal tear (non-detached)
- ☐ Retinal vascular occlusion
- ☐ Other abnormality_____

16. **VISUAL ACUITY in eye that had surgery**

Is vision worse than 6/12 ? ☐ **YES** ☐ **NO** **(GO TO Q.17)**

IF YES: What is the MAIN cause?:

- ☐ Age Related Maculopathy
- ☐ Cystoid macular oedema
- ☐ Posterior capsule opacification
- ☐ Corneal oedema
- ☐ Lens decentration or dislocation
- ☐ Astigmatism
- ☐ Other (*Describe*)_____

17. **CHANGES IN FUNCTIONAL STATUS** (*Tick one*)

- ☐ Improved functional status ⟶ **YES** **NO** (*Tick YES or NO for each*)
- ☐ No change in functional status
- ☐ Worsened functional status (*Describe*)

_____

YES	NO	
☐	☐	Improved activities of daily living
☐	☐	Improved reading ability
☐	☐	Improved driving ability
☐	☐	Improved mobility
☐	☐	Other improvements (*Describe*)_____

_____

18. **FINAL REFRACTION PERFORMED** ☐ **YES** ☐ **NO**

☐ At Hospital ☐ By Local Optometrist

19. **GLASSES DISPENSED** ☐ **YES** ☐ **NO**

☐ At Hospital ☐ By Local Optometrist

20. **DATE EXAMINED** ____ / ____ / **19**__

DAY MONTH YEAR

Thank you for completing this form

Patient ID

5	2	3	8

12-MONTH FOLLOW UP
CLINICAL DATA FORM

Patient Name: _____
Patient Hospital No: _____
Consultant: _____
Hospital: _____

This form should be completed approximately 12 months after surgery.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed; please return to :

Ms P. Courtney
College of Ophthalmologists
17 Cornwall Terrace
Regents Park
London NW1 4QW

Patient ID

5	2	3	8

Cataract Outcome Study

12-Month Follow Up Clinical Data Form - Page 1 of 2

OUTCOME OF CATARACT SURGERY
Day 120 - Day 360 (4 Months to 12 Months)

1. **POSTOPERATIVE EVENTS** (*Tick YES or NO*)

IF YES: *Give date*

YES	NO		DAY MONTH YEAR	YES	NO		DAY MONTH YEAR
☐	☐	Endophthalmitis	I_I_I·I_I_I·I_I_I	☐	☐	Cystoid macular oedema	I_I_I·I_I_I·I_I_I
☐	☐	Wound Leak or rupture	I_I_I·I_I_I·I_I_I	☐	☐	Posterior vitreous detachment	I_I_I·I_I_I·I_I_I
☐	☐	Hyphaema	I_I_I·I_I_I·I_I_I	☐	☐	Posterior capsule opacification	I_I_I·I_I_I·I_I_I
☐	☐	Retinal detachment	I_I_I·I_I_I·I_I_I	☐	☐	Retinal scar or break (no detachment)	I_I_I·I_I_I·I_I_I
☐	☐	IOL dislocation	I_I_I·I_I_I·I_I_I	☐	☐	Intraocular pressure greater than 30 mmHg	I_I_I·I_I_I·I_I_I
☐	☐	IOL removed or exchange	I_I_I·I_I_I·I_I_I	☐	☐	Optic neuropathy	I_I_I·I_I_I·I_I_I
☐	☐	Retained lens material	I_I_I·I_I_I·I_I_I	☐	☐	Other complication (*Specify*)	I_I_I·I_I_I·I_I_I
☐	☐	Inflammation greater than expected	I_I_I·I_I_I·I_I_I			_____	
☐	☐	Iris abnormalities (synechiae; etc)	I_I_I·I_I_I·I_I_I			_____	
☐	☐	Corneal oedema greater than expected peripherally	I_I_I·I_I_I·I_I_I				
☐	☐	Corneal oedema greater than expected centrally	I_I_I·I_I_I·I_I_I				

2. **SUTURES CUT SINCE COMPLETION OF 4-MONTH FOLLOW UP FORM?**

☐ Yes ⟶ Number of visits at which suture(s) were cut:_____

☐ No

3. **POSTERIOR CAPSULOTOMY PERFORMED?**

☐ Yes (DATE: I_I_I·I_I_I·I_I_I) ⟶ If yes: (*Tick one*)
DAY MONTH YEAR

☐ Nd: YAG

☐ Needle/knife

☐ No

4. **CATARACT SURGERY PLANNED IN SECOND EYE?**

☐ No

☐ Yes; planned for (DATE: I_I_I·I_I_I·I_I_I) Yes; planned for date unknown ☐

☐ Already performed (DATE: I_I_I·I_I_I·I_I_I)

5. **BEST CORRECTED DISTANCE ACUITY (SNELLEN)** **RIGHT** 6/I_I_I **LEFT** 6/I_I_I
(Choices: 6/6, 6/9, 6/12, 6/18, 6/24, 6/36, 6/60, 3/60; CF; HM; PL; NPL)

6. **REFRACTION** (In operated eye) +/- I_I·I_I_I+I_I·I_I_IxI_I_I_I
CIRCLE SPHERE CYL AXIS

☐ Not Known

7. **INTRAOCULAR PRESSURE** (applanation) **RIGHT** I_I_Imm **LEFT** I_I_Imm

8. **KERATOMETRY IN DIOPTERS** (in operated eye) I_I_I·I_ID @I_I_I_I°,I_I_I·I_I_ID @I_I_I_I°

☐ Not Known

9. **CORNEAL EXAMINATION** (in operated eye) (*Tick all that apply*)

☐ Normal with secure wound and sutures

☐ Wound gape / leak

☐ Corneal oedema peripherally

☐ Corneal oedema centrally

☐ Broken sutures or protruding ends

☐ Descemet's folds

☐ Descemet's tear or detachment

☐ Other anormality:_____

Patient ID

Cataract Outcome Study

12 Months Follow Up Clinical Data Form - Page 2 of 2

10. **IRIS AND PUPIL** (In operated eye) (*Tick all that apply*)

- ☐ Normal with no iridectomy
- ☐ Normal with surgical iridectomy
- ☐ Non reactive pupil
- ☐ Ectatic or peaked pupil
- ☐ Iris atrophy (including phaco induced)
- ☐ Posterior synechia to capsule or IOL
- ☐ Anterior synechia
- ☐ Afferent pupillary defect
- ☐ Other abnormality:_____

11. **ANTERIOR CHAMBER FINDINGS** (In operated eye) (*Tick all that apply*)

- ☐ Normal
- ☐ Inflammation (cell and flare)
- ☐ Hypopyon
- ☐ Residual lens cortex
- ☐ Hyphaema
- ☐ Other abnormality_____

12. **LENS** (In operated eye) (*Tick all that apply*)

- ☐ Normally centered intraocular lens
- ☐ Edge of optic or dialling hole visible in undilated state
- ☐ Pupillary capture of IOL
- ☐ Posterior displacement of PC IOL optic or haptic
- ☐ Posterior displacement of anterior chamber IOL or haptic
- ☐ Residual lens cortex
- ☐ Other abnormality_____

13. **OPTIC NERVE** (In operated eye) (*Tick all that apply*)

- ☐ Normal
- ☐ Optic atrophy
- ☐ Optic nerve haemorrhage
- ☐ Glaucomatous atrophy
- ☐ Other abnormality_____

14. **MACULA** (In operated eye) *(Tick all that apply)*

- ☐ Normal
- ☐ Angiographic cystoid oedema
- ☐ Clinically significant cystoid oedema
- ☐ Age Related Maculopathy
- ☐ Macular cyst or hole
- ☐ Other abnormality_____

15. **RETINA** (*Tick all that apply*)

- ☐ Normal
- ☐ Retinal Detachment
- ☐ Retinal tear (non-detached)
- ☐ Retinal vascular occlusion
- ☐ Other abnormality_____

16. **VISUAL ACUITY in eye that had surgery**

Is vision worse than 6/12 ? ☐ **YES** ☐ **NO** **(GO TO Q.17)**

IF YES: What is the MAIN cause?:

- ☐ Age Related Maculopathy
- ☐ Cystoid macular oedema
- ☐ Posterior capsule opacification
- ☐ Corneal oedema
- ☐ Lens decentration or dislocation
- ☐ Astigmatism
- ☐ Other (*Describe*)_____

17. **CHANGES IN FUNCTIONAL STATUS** (*Tick one*)

- ☐ Improved functional status ⟶ **YES** **NO** (*Tick YES or NO for each*)
- ☐ No change in functional status
- ☐ Worsened functional status (*Describe*)

_____

YES	NO	
☐	☐	Improved activities of daily living
☐	☐	Improved reading ability
☐	☐	Improved driving ability
☐	☐	Improved mobility
☐	☐	Other improvements (*Describe*)_____

_____

18. **FINAL REFRACTION PERFORMED** ☐ **YES** ☐ **NO**
☐ At Hospital ☐ By Local Optometrist

19. **GLASSES DISPENSED** ☐ **YES** ☐ **NO**
☐ At Hospital ☐ By Local Optometrist

20. **DATE EXAMINED** / / **19**
DAY MONTH YEAR

Appendix B3

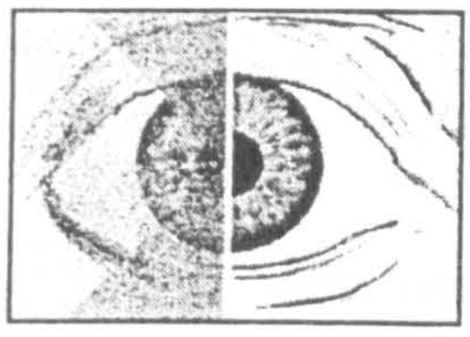
Patient interview booklets :

Pre-operative (baseline)

4 months

12 months

THE CATARACT OUTCOME STUDY



THE WELLHOUSE TRUST

BASELINE PATIENT INTERVIEW

To be completed before the patient has had surgery.

Patient Name: _____

Hospital Number: _____

Consultant: _____

Date of Interview: _____

Interviewer: _____

Patient ID

5	2	3	8

THE CATARACT OUTCOME STUDY
BASELINE PATIENT INTERVIEW

Introduction to Patient.

Hello, my name is _____. I am one of the Cataract Outcome Study team members from the College of Ophthalmologists. You may or may not have received some information about this study.

The study is being conducted at this hospital with the College of Ophthalmologists and has the support of the Department of Health and your eye consultant. It is trying to reach a better understanding of the problems people with cataracts experience in carrying out their daily activities and how the operation changes this. We already have a lot of information on how surgery effects the eye, but there is a great need to advance our knowledge of the patient's experience of the process.

Participation is voluntary. Each person who agrees to take part in the study will be interviewed three times. First before the operation, and then again around 4 and 12 months after the operation.

In the first interview we would ask you questions about your vision, general health, everyday activities and how these are affected by your cataract. You may leave an answer to any of the questions or even leave the study itself at any time.

The interview will take about 45-60 minutes and will be strictly confidential. Your answers will not be seen by your doctor or others who are involved in your medical care. The information provided will go to the College of Ophthalmologists where only the study investigators will have access to it.

We would also like to interview after the operation around 4 and 12 months after surgery, to find out what difference the surgery has made in your ability to see and do your everyday activities, as well as how satisfied you are with the results of the operation.

Would you like to be interviewed ? (For those who have not already indicated they want to take part)

Yes _____ 1
No _____ 2 Reason if any _____

Before you start would please complete this consent form? Please feel free to ask any questions about the study before you sign it.

[Ensure the patient is given an explanatory letter about the study].

THE COLLEGE OF OPHTHALMOLOGISTS
THE CATARACT OUTCOME STUDY.

CONSENT FORM FOR PATIENTS

I, _____ of

_____

give my consent to take part in the Cataract Outcome Study.

The nature of my participation and the purpose of the study have been explained to me by:

_____

I have also received a letter with information about the study.

Signed _____ Date _____

Witness _____ Date _____

COGNITIVE SCALE

IF PATIENT SEEMS TO BE CONFUSED, SEEMS UNABLE TO UNDERSTAND WHAT YOU HAVE SAID TO THEM IN THE INTRODUCTION, OR SEEMS MENTALLY UNABLE TO TAKE PART IN THE INTERVIEW, PLEASE ASK THE FOLLOWING QUESTIONS:

First, I have a few general questions.

		CORRECT	WRONG
1.	What is your full name?	1	2
2.	How old are you?	1	2
3.	When were you born?	1	2
4.	Where were you born?	1	2
5.	What is your mother's first name?	1	2
6.	What is your father's first name?	1	2
7.	Who is the Prime Minister?	1	2
8.	Who was the Prime Minister before this one?	1	2
9.	What year is this?	1	2
10.	What month is this?	1	2
11.	What day of the month is this? (What is the date?)	1	2
12.	What is the name of the city or town you are in?	1	2
13.	What day of the week is it?	1	2
14.	What time is it now?	1	2

BOX 1

IF PATIENT ANSWERS 4 OR MORE QUESTIONS INCORRECTLY, TERMINATE INTERVIEW:

Thank you very much for your help. That is all the information we need. I hope your surgery goes well.
OTHERWISE CONTINUE.

SECTION A: GENERAL QUESTIONS ABOUT VISION

A1. I'd like to start again by asking you some questions about your vision How much trouble do you now have with your vision? Is it none, a little, a moderate amount, or a great deal?

NONE	1
LITTLE	2
MODERATE	3
GREAT DEAL	4

A2. How satisfied are you <u>now</u> with your vision? Are you:

Very satisfied	1
Satisfied	2
Dissatisfied or	3
Very dissatisfied?	4

A3. Have you been told you have a cataract in your right eye, left eye or both eyes?

RIGHT	1
LEFT	2
BOTH	3

A4. Have you ever had surgery for a cataract?

YES	1 (A4a)
NO	2 (A5

BOX 2

A4a. Which eye?

RIGHT	1
LEFT	2

A4b. When?

DATE / /19

TERMINATE INTERVIEW SINCE PATIENT HAS HAD CATARACT SURGERY.

A5 For which eye is cataract surgery scheduled (first)?

RIGHT	1
LEFT	2

A5a. On what date is your cataract surgery scheduled?

DATE / /19	
OR	
DONT KNOW	8

BOX 3

CHECK A3. IF CATARACT IN ONE EYE, SKIP TO A5f. OTHERWISE, CONTINUE.

A5b **IF CATARACT IN BOTH EYES:** Do you think you will have the other cataract removed?

YES	1	
NO	2	(A5e)
DON'T KNOW	3	(A5e)

A5c. Do you know when you will have it removed?

YES	1	
NO	2	(A5e)

A5d. On what date is that surgery planned?

DATE / /19

OR

DON'T KNOW 8

A5e. Who first told you that you had a cataract in the eye you are having the operation on?

Your G.P.	1
An eye doctor	2
Optometrist	3
Other_____	4
Do not know	8

A5f. How long ago was that?

YEARS _____

MONTHS _____

BOX 4

IF LESS THAN 6 MONTHS AGO, SKIP TO A7.
IF 6 MONTHS OR MORE, CONTINUE.

A6. Why did you wait to have the surgery?

_____

_____

_____

A6a. What made you decide to have the surgery now?

_____

_____

_____

A7. Sometimes people tell us that they are having their cataract surgery now because they think something might happen if they waited any longer. Some people think that (READ CHOICES). Do you think that? (CIRCLE "YES" OR "NO" BELOW)

		YES	NO	DON'T KNOW
a.	Do you think the risks of surgery would be greater if you wait?	1	2	8
b.	Do you think the improvement in your vision due to surgery will be greater now than it would be if you delayed the surgery?	1	2	8
c.	You might become permanently blind if you delayed the surgery	1	2	8
d.	You thought you had to wait until your cataract was "ripe"	1	2	8
e.	The risks of surgery would be lower the longer you wait	1	2	8

A8. Do you think anything else other than what we have mentioned would happen?

YES	1	
NO	2	(A9)
DONT KNOW	8	(A9)

A8a. What do you think would happen?

_____

_____

A9. Have you been on any other waiting list for your cataract operation?

YES	1 ⟶	Where? _____
NO	2	How long? _____

A9a. How long have you waited for surgery at this hospital? _____

A9b. How concerned were you about having to wait that time?

not at all	1
a little	2
a moderate amount	3
a great deal	4

A9c. Can you tell me if there is anything in particular that worries you / bothers you about waiting?

_____

A10. Do you currently <u>wear</u> glasses or contact lenses?

YES	1	(A10a)
NO	2	(A11)

A10a. Do you wear them for reading, to see things that are far away, or both? (IF PATIENT SAYS "BIFOCAL", CIRCLE BOTH)

READING	1
FAR AWAY	2
BOTH	3

A11. During the past month have you been bothered by any of the following symptoms in your eye that is scheduled for cataract surgery? (CIRCLE BELOW)

IF YES: ASK:

A. Are you being treated for this problem? (CIRCLE BELOW)

B. Do you think there is more than a 50-50 chance that this will improve after your cataract surgery? (CIRCLE BELOW)

IF YES

C. How much improvement do you expect after your cataract surgery? Do you expect a little, a moderate amount or a great deal of improvement? (CIRCLE BELOW)

		BOTHERED		(A) TREATMENT		(B) EXPECT TO IMPROVE			(C) IF YES: IMPROVEMENT EXPECTED			
		YES	NO	YES	NO	YES	NO	DK	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DK
A12.	Red painful or tender eye	1	2	1	2	1	2	8	1	2	3	8
A13.	Feeling as if something were in your eye	1	2	1	2	1	2	8	1	2	3	8
A14.	Watery burning or itching eye	1	2	1	2	1	2	8	1	2	3	8
A15.	Double vision or distorted vision	1	2	1	2	1	2	8	1	2	3	8
A16.	A drooping eyelid	1	2	1	2	1	2	8	1	2	3	8
A17.	Spots floating before your eye	1	2	1	2	1	2	8	1	2	3	8
A18.	Glare halo or seeing rings around light	1	2	1	2	1	2	8	1	2	3	8
A19.	Blurry vision with your most recent glasses	1	2	1	2	1	2	8	1	2	3	8
A20.	Things seeming brighter than they used to in a way that is disturbing	1	2	1	2	1	2	8	1	2	3	8
A21.	Colours looking different than they used to in a way that is disturbing	1	2	1	2	1	2	8	1	2	3	8
A22.	A worsening of your vision in the past month in the eye having surgery	1	2	1	2	1	2	8	1	2	3	8

A23. Do you have any other eye problems, conditions, or symptoms?

YES	1	
NO	2	(A24)

A23a. What are these? (RECORD UP TO 3)

1._____

2._____

3._____

A24. Do you currently drive a car?

YES	1	(A28)
NO	2	

A25. Have you ever driven a car?

YES	1	
NO	2	(A34)

A26. When did you stop driving?

LESS THAN 6 MONTHS AGO	1
6-12 MONTHS AGO	2
MORE THAN 12 MONTHS AGO	3

A27. Why did you stop driving?

VISION	1	(A30)
OTHER ILLNESS	2	(A30)
OTHER REASON	3	(A30)

A28. How much difficulty do you have driving during the day because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4

A29. How much difficulty do you have driving at night because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4
DO NOT DRIVE AT NIGHT	5

A30. During the past year have you been involved in any road traffic accidents while you were driving?

YES 1 (A31)
NO 2 (A34)
DID NOT DRIVE DURING PAST YEAR 3 (A34)

	(A)FIRST	(B) SECOND
A31. What kind of accident?	_____ _____ _____	_____ _____ _____
A32. Do you think this was because of your vision? YES NO	1 2	1 (A34) 2 (A34)
A33. Were there any others? YES NO	1 (A31B) 2 (A34)	

A34. Now I'd like to ask you about injuries or accidents that people sometimes have. During the past year did you have any injuries or accidents, such as cuts, bruises, or falls?

YES 1
NO 2(A35)

	(A)FIRST	(B) SECOND
A34a. What kind of accident? Probe for following: 1. Type of injury eg. burn 2. Site of injury eg. arm / leg 3. How injury occured eg. iron	1_____ 2_____ 3_____	1_____ 2_____ 3_____
A34b. Do you think this was because of your vision? YES NO	1 2	1 2
A34c. Were there any other accidents / injuries this year ? YES NO	1 (A34aB) 2	

A35. Poor eyesight may prevent you from doing some activities. I would like you to think of any activities that you are limited in doing because of your eyesight - this could include household activities, work, hobbies, social, or outdoor activities. Of the activities you may be limited in doing because of your vision which are the <u>three</u> that are most important to you?

If response is "dont know" prompt with the above again

A. Let's start with the most important. (RECORD BELOW)

B. How about the second most important? (RECORD BELOW)

C. How about the third most important? (RECORD BELOW)

AFTER RECORDING ACTIVITIES, ASK A36-A38 (AS APPROPRIATE) FOR EACH

	(A) NONE ☐ MOST IMPORTANT	(B) ONLY ONE ☐ SECOND MOST IMPORTANT	(C) ONLY TWO ☐ THIRD MOST IMPORTANT
A36. Thinking about (ACTIVITY), how much difficulty do you presently have with that? Do you have:			
A little	1	1	1
A moderate amount	2	2	2
A great deal, or	3	3	3
Are you unable to do it?	4	4	4
A37. Do you expect to be able to do (ACTIVITY) or do it with less difficulty after your cataract surgery? (EYE TO BE OPERATED ON)			
YES	1	1	1
NO	2 (A36 FOR B)	2 (A36 FOR C)	2 (A39)
A38. How much improvement in (ACTIVITY) do you expect after your cataract surgery? Do you expect:			
A little,	1	1	1 (A39)
A moderate amount, or	2	2	2 (A39)
A great deal?	3	3	3 (A39)
DON'T KNOW	8	8	8 (A39)

A39. Do you have any difficulty even with glasses in doing any of the following activities? (CIRCLE BELOW. IF PATIENT STATES S/HE DOES NOT DO THAT ACTIVITY, CIRCLE N/A FOR NOT APPLICABLE)

IF YES: ASK:

A. How much difficulty do you currently have: A little, a moderate amount, a great deal or are you unable to do (INSERT ACTIVITY)? (CIRCLE BELOW)

B. Do you think there is more than a 50-50 chance that this will improve after your surgery? (CIRCLE BELOW)

IF YES

C. How much improvement do you expect after your cataract surgery? Do you expect a little, a moderate amount or a great deal of improvement? (CIRCLE BELOW)

		DIFFICULTY			(A) IF YES: HOW MUCH				(B) EXPECT TO IMPROVE			(C) IF YES: IMPROVEMENT EXPECTED			
		Yes	No	N/A	A LITTLE	MODERATE AMOUNT	GREAT DEAL	UNABLE TO DO	Yes	No	DK	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DK
A40	Reading small print such as labels on medicine bottles,a telephone book, food labels	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A41	Reading a newspaper or a book	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A42	Reading a large print book print or large print newspaper or numbers on a telephone	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A43	Recognizing people when they are close to you	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A44	Seeing steps, stairs or kerbs	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A45	Reading traffic signs, street signs, shop signs	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A46	Doing fine handwork like sewing, knitting, crocheting, carpentry	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A47	Writing letters, cheques, or filling out forms	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A48	Playing games such as bingo, dominos, card games	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A49	Taking part in sports like bowling, handball, tennis, golf	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A50	Cooking	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A51	Watching television	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A52	Getting about indoors	1	2	3	1	2	3	4	1	2	8	1	2	3	8
A53	Getting about outdoors	1	2	3	1	2	3	4	1	2	8	1	2	3	8

SECTION B: SATISFACTION WITH CARE

Thinking about the medical care you are receiving for your cataracts from all of the doctors caring for your eyes, would you rate the following as excellent, very good, good, fair, or poor? (CIRCLE ANSWER)

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DON'T KNOW
B1.	Attention your eye doctor(s) gave to what you had to say	1	2	3	4	5	7	8
B2.	Amount of time you had with your eye doctor(s) during a visit	1	2	3	4	5	7	8
B3.	Amount of time you had with your eye doctor(s)'staff during a visit	1	2	3	4	5	7	8
B4.	Friendliness and courtesy shown to you by your eye doctor(s)	1	2	3	4	5	7	8
B5.	Friendliness and courtesy shown to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B6.	Your eye doctor(s)' personal interest in you and your medical problems	1	2	3	4	5	7	8
B7.	Reassurance and support offered to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B8.	Consideration of your personal needs and wants in deciding <u>whether</u> to perform cataract surgery	1	2	3	4	5	7	8
B9.	The amount of time you were given to think about <u>whether</u> you wanted to undergo cataract surgery	1	2	3	4	5	7	8
B10.	The opportunity you had to ask all the questions you wanted to about your cataracts and cataract surgery	1	2	3	4	5	7	8
B11	.The answers your doctor(s) gave to all the questions you asked about your cataract and cataract surgery	1	2	3	4	5	7	8

B12. Some doctors explain more things to patients than other doctors. We would like you to tell us whether your eye doctor(s) or anyone in their hospital explained the following things to you. Did you receive: (CONTINUE WITH B13)

A. **FOR EACH ITEM ANSWERED YES, ASK:**
Was the explanation excellent, very good, good, fair, or poor?

				IF YES: RATING OF EXPLANATION					
		YES	NO	EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DON'T KNOW
B13.	Explanations of procedures and tests performed before your cataract surgery	1	2	1	2	3	4	5	8
B14.	An explanation of the likely benefits of cataract surgery	1	2	1	2	3	4	5	8
B15.	An explanation of possible harm the cataract surgery might do	1	2	1	2	3	4	5	8
B16.	An explanation about what might happen if you did not have the cataract surgery when it was recommended	1	2	1	2	3	4	5	8
B16a	An explanation about the waiting time that you will have before surgery	1	2	1	2	3	4	5	8
B17.	An explanation about which activities you probably would be able to do after you had your cataract surgery	1	2	1	2	3	4	5	8
B18.	An explanation about which activities you probably would still have trouble doing after your cataract surgery	1	2	1	2	3	4	5	8
B19.	An explanation of how you would probably feel during the first night and day after you had your cataract surgery	1	2	1	2	3	4	5	8
B20.	An explanation of how much help you would need during the first few days after your cataract surgery	1	2	1	2	3	4	5	8
B21.	An explanation about how long it would take to recover completely from your cataract surgery	1	2	1	2	3	4	5	8
B22.	An explanation about when your eye doctor(s) wanted you to come back for a check-up after your surgery	1	2	1	2	3	4	5	8
B23.	An explanation about what problemsyour eye doctor(s) would like you to call him or her about	1	2	1	2	3	4	5	8

Thinking about the medical care you are receiving for your cataracts from all of the doctors caring for your eyes, would you rate the following excellent, very good, good, fair, or poor? (CIRCLE ANSWER).

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DONT KNOW
B24	Once you and your doctor(s) decided you should have cataract surgery, the amount of time you had to wait before surgery could be done	1	2	3	4	5	7	8
B25	Convenience of the hospital location	1	2	3	4	5	7	8
B26	Hours when hospital visits can be scheduled	1	2	3	4	5	7	8
B27	How easy it was to get back and forth from your cataract surgery	1	2	3	4	5	7	8
B28	Arrangements for making appointments by phone	1	2	3	4	5	7	8
B29	Length of time you wait for your first visit to Out patient Eye Dept.	1	2	3	4	5	7	8
B30	Length of time spent waiting at the hospital to see your eye doctor(s) at that visit	1	2	3	4	5	7	8
B31	Availability of information or advice by phone	1	2	3	4	5	7	8
B32	How easy it is for you to reach your eye doctor(s) or their nurse if you need to talk to them	1	2	3	4	5	7	8
B33	The thoroughness of the eye examination(s) when you were told you needed a cataract operation	1	2	3	4	5	7	8
B34	Thoroughness of the examination of your overall health	1	2	3	4	5	7	8
B35	Completeness and quality of your eye doctor(s) department and facilities	1	2	3	4	5	7	8
B36	All things considered, the care I have received for my cataract(s) has been	1	2	3	4	5	7	8
B37	Now, thinking about all the medical care that you receive, would you rate that as	1	2	3	4	5	7	8

SECTION C: GENERAL HEALTH STATUS

C1. In general, would you say your health is excellent, very good, good, fair, or poor?

EXCELLENT	1	(C2)
VERY GOOD	2	(C2)
GOOD	3	(C2)
FAIR	4	(C1a)
POOR	5	(C1a)

C1a. Do you rate your health as (fair/poor) because of your vision?

YES	1	
NO	2	(C2)

C1b. Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

YES	1	
NO	2	(C2)

C1c. How much improvement in your health do you expect after your cataract surgery? Do you expect:

A little,	1
A moderate amount, or	2
A great deal?	3
DONT KNOW	8

C2. <u>Compared to other people your own age</u>, how would you rate your health? Would you say it is:

Much better,	1	(C3)
Somewhat better,	2	(C3)
About the same,	3	(C3)
Somewhat worse, or	4	(C2a)
Much worse?	5	(C2a)

C2a. Do you think your health is (somewhat/much) worse than others your own age because of your vision?

YES	1	
NO	2	(C3)

C2b. Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

YES	1	
NO	2	(C3)

C2c. How much improvement do you expect after your cataract surgery?

A little,	1
A moderate amount, or	2
A great deal?	3
DON'T KNOW	8

C3. At the moment do you have any other health problems that you may need to see a doctor about regularly?
[Allow the patient to respond freely first, ticking off any conditions mentioned on the list below]. Then ask:

At the moment do you have any of the following conditions or symptoms?

IF YES:

A. How much does it interfere with your activities: Not at all, a little (some), or a great deal?

				(A) **IF YES:** How much does it interfere?		
		YES	NO	NOT AT ALL	A LITTLE	A GREAT DEAL
C4.	Stomach, bowel or intestinal trouble	1	2	1	2	3
C5.	Trouble with bladder, urine, kidneys	1	2	1	2	3
C6.	**FOR WOMEN:** Diseases of the ovaries or uterus	1	2	1	2	3
C7.	**FOR MEN:** Prostate trouble	1	2	1	2	3
C8.	Serious trouble with one or both ears or trouble with hearing	1	2	1	2	3
C9.	Frequent trouble with gums or mouth	1	2	1	2	3
C10.	Frequent foot trouble (for example, bunions, in growing toenails)	1	2	1	2	3
C11.	Frequent skin trouble (for example, eczema)	1	2	1	2	3
C12.	Anaemia (low red blood cell count)	1	2	1	2	3
C13.	Phlebitis or thrombophlebitis or blood clot in veins or arteries	1	2	1	2	3
C14.	High blood pressure or hypertension	1	2	1	2	3
C15.	Any heart trouble, hardening of arteries (arteriosclerosis) or effects of heart attack, angina	1	2	1	2	3
C16.	Effects of a stroke or cerebrovascular disease	1	2	1	2	3
C17.	Diabetes	1	2	1	2	3
C18.	Cancer or malignant tumour or growth	1	2	1	2	3
C19.	Recurring gall bladder or liver trouble	1	2	1	2	3
C20	Haemorrhoids or piles	1	2	1	2	3
C21.	Repeated attacks of sinus trouble	1	2	1	2	3
C22.	Hay fever or other allergy	1	2	1	2	3
C23.	Thyroid trouble or goitre	1	2	1	2	3

				(A) IF YES: How much does it interfere?		
		YES	NO	NOT AT ALL	A LITTLE	A GREAT DEAL
C24.	Emotional, nervous or mental problem	1	2	1	2	3
C25.	Arthritis, rheumatism, bursitis	1	2	1	2	3
C26.	Paralysis	1	2	1	2	3
C27.	Repeated trouble with back or spine	1	2	1	2	3
C28.	Trouble with circulation in arms or legs	1	2	1	2	3
C29.	Oedema or water retention	1	2	1	2	3
C30.	Effects of fractured or broken bones	1	2	1	2	3
C31.	Asthma	1	2	1	2	3
C32.	Chronic bronchitis or emphysema	1	2	1	2	3
C33.	Tuberculosis	1	2	1	2	3
C34.	Some other major problem (SPECIFY) _____	1	2	1	2	3

SECTION D: MEDICAL CARE

D1. Now I would like to ask you about the medical care you have received during the past six months - that is from (DATE 6 MONTHS AGO) until now. In the past 6 months, have you been admitted to a hospital as an <u>inpatient</u> - either for an overnight stay or for a "same day" procedure?

YES	1	
NO	2	(D2)

D1a. On how many different occasions have you been admitted to the hospital as an inpatient in the past 6 months?

NUMBER OF OCCASIONS:

D1b. Including all these occasions, how many nights have you spent in a hospital in the past 6 months?

NUMBER OF NIGHTS:

D2. Have you been a patient in a hospital casualty department during the past 6 months? (Do not count the instances in which you have been hospitalized)

YES	1	
NO	2	(D3)

D2a. How many times have you been a patient in a hospital casualty department in the past 6 months?

NUMBER OF TIMES:

D3. In the past 6 months, have you been an outpatient in a hospital or visited a hospital clinic? (Do not count casualty department visits or visits to eye doctor or eye clinics)

YES	1	
NO	2	(D4)

D3a. How many times have you been an outpatient or visited a hospital clinic in the past 6 months? (Do not count casualty department visits or visits to eye doctors or eye clinics)

NUMBER OF TIMES:

D4. Now I would like to know how many times you have seen your G.P. in the past 6 months?

NUMBER OF TIMES:

D5. Over the past 6 months, how many times have you seen each of the following?

a. Your eye consultant?: _____

b. An optometrist?: _____

c. Any other eye doctor?: _____

NOW I WOULD LIKE TO ASK YOU ABOUT THE SERVICES THAT YOU HAVE RECEIVED IN YOUR HOME.

D6. Over the past 6 months, have you received any of these ("SERVICE") in your home? _____(CIRCLE BELOW)

For each answered YES ask how many times did you use this service in the past 2 weeks?

		(A) RECEIVED (6 Months)			(B) IF YES, HOW MANY TIMES? (Past 2 Weeks)	
	SERVICES	YES	NO	DK		DK
D7	District Nurse	1	2	8	_____	8
D8	Homecare services - home help to do cleaning / laundry	1	2	8	_____	8
D9	Assistance from relatives or friends? (Shopping, cleaning, driving)	1	2	8	_____	8
D10	Assistance with meal preparation or delivery of meals (meals on wheels)	1	2	8	_____	8
D11	Other _____	1	2	8	_____	8

SECTION E: WAITING TIME

Now I'd like to ask some general questions about the time that people must wait before surgery. We are interested in how patients generally feel about the topic of waiting times, and particularly for cataract surgery.

E1. Presently there are waiting times for patients who are going to have many types of surgery:

		No Wait	1-3 MOS	4-6 MOS	7-12 MOS	1-2 YEARS	MORE THAN 2 YEARS	DK
E1a	In general what do you think is the maximum time that is reasonable for people to have to wait before having an operation that is not an emergency?	1	2	3	4	5	6	8
E1b	What is the maximum time that you think people should have to wait for heart surgery that is not an emergency?	1	2	3	4	5	6	8
E1c	What is the maximum time you think people should have to wait for hip surgery?	1	2	3	4	5	6	8
E1d	What is the maximum time that you think people should have to wait for cataract surgery?	1	2	3	4	5	6	8

E2. What do you believe is the main reason for waiting times for cataract surgery? (CIRCLE ONE RESPONSE)

SHORTAGE OF BEDS	1
SHORTAGE OF OPERATING SPACE/TIME	2
SHORTAGE OF DOCTORS OR SPECIALISTS	3
HIGH DEMAND FOR OPERATIONS/HIGH NUMBER OF PATIENTS	4
OVERUSE/ABUSE OF HEALTH SYSTEM	5
SHORTAGE OF FUNDS/GOVERNMENT CUTS	6

OTHER (specify)_____

SECTION F: BACKGROUND SECTION

F1. I'd like to ask you some general background questions. Are you currently:

Married,	1
Widowed,	2
Divorced,	3
Separated, or	4
Have you never been married?	5

F2. Are you living alone, with friends or family, or somewhere else?

ALONE	1
FRIENDS OR FAMILY	2
SOMEWHERE ELSE (SPECIFY)	3

F3. How old are you?

AGE:

F4. What kind of housing do you live in?

Own home / flat	1
Rented house / flat	2
Council house / flat	3
Nursing home	4
Sheltered accomodation	5

F5. What (is/was) your occupation for most of your life?

OCCUPATION:

SECTION G: Time Trade Off Scenario.

1. How long do you usually spend sleeping (both day and night)?

Hours _____
Minutes _____

2. If you have difficulty sleeping, how much sleep do you think you need in total, (both day and night)?

Hours _____
Minutes _____

I am going to read you a description of someone who takes an IMAGINARY cure before you answer the remaining questions.

Think of someone who has difficulty in seeing, their vision is blurred so that they cannot read bus numbers. They also have difficulty making out faces on television. Imagine that this person is given a cure that will completely restore their eyesight. The cure has just one snag, the person must spend extra time sleeping to rest their eyes. The cure has no other side effects, it is not painful or unpleasant in any way, it just requires the person to give up some time to improve their eyesight. Of course this means that they will have less time each day to do the things they enjoy, but, when they are awake, they will have perfect eyesight to do whatever they wish.

Now please forget the person in the story. We are interested in finding out about YOU and YOUR eyesight.

Please spend a little time thinking about the benefits that improved vision would bring to you.

3. What things would you be able to do if your eyesight is improved?

_____

4. Would you be prepared to give up some time to improve your eyesight?

Yes / No

If "NO" skip next question

5. How much EXTRA time would you be prepared to spend sleeping (either during the day or at night) to have perfect eyesight? (Please be as precise as possible)

Hours _____
Minutes _____

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

Before beginning the next part of this interview, I am going to read you some instructions.

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out, you may do some for shorter lengths of time, you may do some in different ways. These changes in your activities might be recent or long standing. We are interested in learning about any changes that describe you today and are related to your state of health.

I will be reading statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand about because they describe you today and are related to your state of health. As I read the questions, think of yourself today. I will pause briefly after each statement. When you hear one that does describe you and is related to health please tell me and I will check it.

Let me give you an example. I might read the statement "I am not driving my car". If this statement is related to your health and describes you today, you should tell me. Also, if you have not been driving for some time because of your health, and are still not driving today, you should answer "yes" to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not respond to it. If you simply are driving less, or are driving shorter distances, and feel that the statement only partially describes you, please do not respond to that statement as well.

Please tell me if you want me to slow down, repeat a statement, or stop so that you can think about one. Also let me know any time you would like to review the instructions. Remember we are interested in the recent or long standing changes in your activities that are related to your health.

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

H1. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H2)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **<u>IF YES:</u>** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		YES →	NO →	YES →	NO →	YES →	NO →	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H2.	I spend much of the day lying down in order to rest	1	2	1	2	1	2	1	2	3	8
H3.	I sit during much of the day	1	2	1	2	1	2	1	2	3	8
H4.	I am sleeping or dozing most of the time day and night	1	2	1	2	1	2	1	2	3	8
H5.	I lie down more often during the day in order to rest	1	2	1	2	1	2	1	2	3	8
H6.	I sit around half-asleep	1	2	1	2	1	2	1	2	3	8
H7.	I sleep less at night, for example,wake up too early, don't fall asleep for a long time, awaken frequently	1	2	1	2	1	2	1	2	3	8
H8.	I sleep or nap more during the day	1	2	1	2	1	2	1	2	3	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H9. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H10)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H10.	I say how bad or useless I am, for example, that I am a burden on others	1	2	1	2	1	2	1	2	3	8
H11.	I laugh or cry suddenly	1	2	1	2	1	2	1	2	3	8
H12.	I often moan and groan in pain or discomfort	1	2	1	2	1	2	1	2	3	8
H13.	I have attempted suicide	1	2	1	2	1	2	1	2	3	8
H14.	I act nervous or restless	1	2	1	2	1	2	1	2	3	8
H15.	I keep rubbing or holding areas of my body that hurt or are uncomfortable	1	2	1	2	1	2	1	2	3	8
H16.	I act irritable and impatient with myself, for example, talk badly about myself, swear at myself,blame myself for things that happen	1	2	1	2	1	2	1	2	3	8
H17.	I talk about the future in a hopeless way	1	2	1	2	1	2	1	2	3	8
H18.	I get sudden fright	1	2	1	2	1	2	1	2	3	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H19. Please remember to answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H20)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **<u>IF YES:</u>** How much improvement do you expect after your cataract surgery. A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱→ YES	⟶ NO	↱→ YES	⟶ NO	↱→ YES	⟶ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H20	I make difficult moves with help,for example, getting into or out of cars, bathtubs	1	2	1	2	1	2	1	2	3	8
H21	I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid	1	2	1	2	1	2	1	2	3	8
H22	I stand only for short periods of time	1	2	1	2	1	2	1	2	3	8
H23	I do not maintain balance	1	2	1	2	1	2	1	2	3	8
H24	I move my hands or fingers with some limitation or difficulty	1	2	1	2	1	2	1	2	3	8
H25	I stand up only with someone's help	1	2	1	2	1	2	1	2	3	8
H26	I kneel, stop, or bend down only by holding on to something	1	2	1	2	1	2	1	2	3	8
H27	I am in a restricted position all the time	1	2	1	2	1	2	1	2	3	8
H28	I am very clumsy in body movements	1	2	1	2	1	2	1	2	3	8
H29	I get in and out of bed or chairs by grasping something for support or using a stick or zimmer walking frame	1	2	1	2	1	2	1	2	3	8
H30	I stay lying down most of the time	1	2	1	2	1	2	1	2	3	8
H31	I change position frequently	1	2	1	2	1	2	1	2	3	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱→ YES	→ NO	↱→ YES	→ NO	↱→ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H32	I hold onto something to move myself around in bed	1	2	1	2	1	2	1	2	3	8
H33	I do not bathe myself completely, for example, require assistance with bathing	1	2	1	2	1	2	1	2	3	8
H34	I do not bathe myself at all, but am bathed by someone else	1	2	1	2	1	2	1	2	3	8
H35	I use bedpan with assistance	1	2	1	2	1	2	1	2	3	8
H36	I have trouble getting shoes, socks, or stockings on	1	2	1	2	1	2	1	2	3	8
H37	I do not have control of my bladder	1	2	1	2	1	2	1	2	3	8
H38	I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces	1	2	1	2	1	2	1	2	3	8
H39	I spend most of the time partly undressed or in pyjamas	1	2	1	2	1	2	1	2	3	8
H40	I do not have control of my bowels	1	2	1	2	1	2	1	2	3	8
H41	I dress myself, but do so very slowly	1	2	1	2	1	2	1	2	3	8
H42	I get dressed only with someone's help	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H43. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H44)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **<u>IF YES:</u>** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H44	I do work around the house only for short periods of time or rest often	1	2	1	2	1	2	1	2	3	8
H45	I am doing <u>less</u> of the regular daily work around the house than I would usually do	1	2	1	2	1	2	1	2	3	8
H46	I am not doing <u>any</u> of the regular daily work around the house that I would usually do	1	2	1	2	1	2	1	2	3	8
H47	I am not doing <u>any</u> of the maintenance or repair work that I would usually do in my home or yard	1	2	1	2	1	2	1	2	3	8
H48	I am not doing <u>any</u> of the shopping that I would usually do	1	2	1	2	1	2	1	2	3	8
H49	I am not doing <u>any</u> of the house cleaning that I would usually do	1	2	1	2	1	2	1	2	3	8
H50	I have difficulty doing handwork, for example, turning taps, using kitchen gadgets, sewing, carpentry	1	2	1	2	1	2	1	2	3	8
H51	I am not doing <u>any</u> of the clothes washing that I would usually do	1	2	1	2	1	2	1	2	3	8
H52	I am not doing heavy work around the house	1	2	1	2	1	2	1	2	3	8
H53	I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget	1	2	1	2	1	2	1	2	3	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H54. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H55)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		YES	NO	YES	NO	YES	NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H55	I am getting around only within one building	1	2	1	2	1	2	1	2	3	8
H56	I stay within one room	1	2	1	2	1	2	1	2	3	8
H57	I am staying in bed more	1	2	1	2	1	2	1	2	3	8
H58	I am staying in bed most of the time	1	2	1	2	1	2	1	2	3	8
H59	I am not now using public transportation	1	2	1	2	1	2	1	2	3	8
H60	I stay home most of the time	1	2	1	2	1	2	1	2	3	8
H61	I am only going to places with toilets nearby	1	2	1	2	1	2	1	2	3	8
H62	I am not going into town	1	2	1	2	1	2	1	2	3	8
H63	I stay away from home only for brief periods of time	1	2	1	2	1	2	1	2	3	8
H64	I do not get around in the dark or in unlit places without someone's help	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H65. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H66)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H66	I am going out less to visit people	1	2	1	2	1	2	1	2	3	8
H67	I am not going out to visit people at all	1	2	1	2	1	2	1	2	3	8
H68	I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help	1	2	1	2	1	2	1	2	3	8
H69	I often act irritable toward those around me, for example, snap at people, give sharp answers, criticise easily	1	2	1	2	1	2	1	2	3	8
H70	I show less affection	1	2	1	2	1	2	1	2	3	8
H71	I am doing fewer social activities with groups of people	1	2	1	2	1	2	1	2	3	8
H72	I am cutting down the length of visits with friends	1	2	1	2	1	2	1	2	3	8
H73	I am avoiding social visits from others	1	2	1	2	1	2	1	2	3	8
H74	My sexual activity is decreased	1	2	1	2	1	2	1	2	3	8
H75	I often express concern over what might be happening to my health	1	2	1	2	1	2	1	2	3	8
H76	I talk less with those around me	1	2	1	2	1	2	1	2	3	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H77	I make many demands, for example, insist that people do things for me, tell them how to do things	1	2	1	2	1	2	1	2	3	8
H78	I stay alone much of the time	1	2	1	2	1	2	1	2	3	8
H79	I act disagreeable to family members, for example, I act spiteful, I am stubborn	1	2	1	2	1	2	1	2	3	8
H80	I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them	1	2	1	2	1	2	1	2	3	8
H81	I isolate myself as much as I can from the rest of the family	1	2	1	2	1	2	1	2	3	8
H82	I am paying less attention to the children	1	2	1	2	1	2	1	2	3	8
H83	I refuse contact with family members, for example, turn away from them	1	2	1	2	1	2	1	2	3	8
H84	I am not doing the things I usually do to take care of my children or family	1	2	1	2	1	2	1	2	3	8
H85	I am not joking with family members as I usually do	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H86. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H87)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **<u>IF YES:</u>** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H87	I walk shorter distances or stop to rest often	1	2	1	2	1	2	1	2	3	8
H88	I do not walk up or down hills	1	2	1	2	1	2	1	2	3	8
H89	I use stairs only with mechanical support, for example, handrail, walking stick, crutches	1	2	1	2	1	2	1	2	3	8
H90	I walk up or down stairs only with assistance from someone else	1	2	1	2	1	2	1	2	3	8
H91	I get around in a wheelchair	1	2	1	2	1	2	1	2	3	8
H92	I do not walk at all	1	2	1	2	1	2	1	2	3	8
H93	I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg	1	2	1	2	1	2	1	2	3	8
H94	I walk only with help from someone	1	2	1	2	1	2	1	2	3	8
H95	I go up and down stairs more slowly, for example, stop often, one step at a time	1	2	1	2	1	2	1	2	3	8
H96	I do not use stairs at all	1	2	1	2	1	2	1	2	3	8
H97	I get around only by using a zimmer frame, crutches, cane, walls, or furniture	1	2	1	2	1	2	1	2	3	8
H98	I walk more slowly	1	2	1	2	1	2	1	2	3	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H99. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H100)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	⟶ NO	↱ YES	⟶ NO	↱ YES	⟶ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H100	I am confused and start several actions at a time	1	2	1	2	1	2	1	2	3	8
H101	I have more minor accidents, for example, drop things, trip and fall, bump into things	1	2	1	2	1	2	1	2	3	8
H102	I react slowly to things that are said or done	1	2	1	2	1	2	1	2	3	8
H103	I do not finish things I start	1	2	1	2	1	2	1	2	3	8
H104	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things	1	2	1	2	1	2	1	2	3	8
H105	I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is	1	2	1	2	1	2	1	2	3	8
H106	I forget a lot, for example, things that happened recently, where I put things, appointments	1	2	1	2	1	2	1	2	3	8
H107	I do not keep my attention on any activity for long	1	2	1	2	1	2	1	2	3	8
H108	I make more mistakes than usual	1	2	1	2	1	2	1	2	3	8
H109	I have difficulty doing activities involving concentration and thinking	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H110. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H111)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		YES	NO	YES	NO	YES	NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H111	I am having trouble writing or typing	1	2	1	2	1	2	1	2	3	8
H112	I communicate mostly by gestures, for example, moving head, pointing, sign language	1	2	1	2	1	2	1	2	3	8
H113	My speech is understood only by a few people who know me well	1	2	1	2	1	2	1	2	3	8
H114	I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly	1	2	1	2	1	2	1	2	3	8
H115	I don't write except to sign my name	1	2	1	2	1	2	1	2	3	8
H116	I carry on conversation only when very close to the other person or looking at him	1	2	1	2	1	2	1	2	3	8
H117	I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words	1	2	1	2	1	2	1	2	3	8
H118	I am understood with difficulty	1	2	1	2	1	2	1	2	3	8
H119	I do not speak clearly when I am under stress	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H120. The next group of statements has to do with any work you usually do other than managing your home. By this we mean anything that you regard as work that you do on a regular basis. Do you usually do work other than managing your home?

YES	1	(H124)
NO	2	

H121. Are you retired?

YES	1	
NO	2	(H134)

H122. Is your retirement related to your health?

YES	1	
NO	2	(H134)

H123. Is your retirement related to your vision?

YES	1	(H134)
NO	2	(H134)

A39. Do you have any difficulty even with glasses in doing any of the following activities? (CIRCLE BELOW. IF PATIENT STATES S/HE DOES NOT DO THAT ACTIVITY, CIRCLE N/A FOR NOT APPLICABLE)

IF YES: ASK:

A. How much difficulty do you currently have: A little, a moderate amount, a great deal or are you unable to do (INSERT ACTIVITY)? (CIRCLE BELOW)
B. Has this improved since your cataract operation? (CIRCLE BELOW)

IF YES

C. Did this improve as much as you expected it would after your cataract operation? (CIRCLE BELOW)

		DIFFICULTY			(A) IF YES: HOW MUCH				(B) IMPROVED			(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED	
		Yes	No	N/A	A LITTLE	MODERATE AMOUNT	GREAT DEAL	UNABLE TO DO	Yes	No	DK	Yes	No
A40	Reading small print such as labels on medicine bottles,a telephone book, food labels	1	2	3	1	2	3	4	1	2	8	1	2
A41	Reading a newspaper or a book	1	2	3	1	2	3	4	1	2	8	1	2
A42	Reading a large print book print or large print newspaper or numbers on a telephone	1	2	3	1	2	3	4	1	2	8	1	2
A43	Recognizing people when they are close to you	1	2	3	1	2	3	4	1	2	8	1	2
A44	Seeing steps, stairs or kerbs	1	2	3	1	2	3	4	1	2	8	1	2
A45	Reading traffic signs, street signs, shop signs	1	2	3	1	2	3	4	1	2	8	1	2
A46	Doing fine handwork like sewing, knitting, crocheting, carpentry	1	2	3	1	2	3	4	1	2	8	1	2
A47	Writing letters, cheques, or filling out forms	1	2	3	1	2	3	4	1	2	8	1	2
A48	Playing games such as bingo, dominos, card games	1	2	3	1	2	3	4	1	2	8	1	2
A49	Taking part in sports like bowling, handball, tennis, golf	1	2	3	1	2	3	4	1	2	8	1	2
A50	Cooking	1	2	3	1	2	3	4	1	2	8	1	2
A51	Watching television	1	2	3	1	2	3	4	1	2	8	1	2
A52	Getting about indoors	1	2	3	1	2	3	4	1	2	8	1	2
A53	Getting about outdoors	1	2	3	1	2	3	4	1	2	8	1	2

H134. This group of statements has to do with activities you usually do in your free time. These activities are things that you might do for relaxation, to pass the time, or for entertainment. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **IF YES:** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		YES	NO	YES	NO	YES	NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H135	I do my hobbies and recreation for shorter periods of time	1	2	1	2	1	2	1	2	3	8
H136	I am going out for entertainment less often	1	2	1	2	1	2	1	2	3	8
H137	I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	3	8
H138	I am not doing any of my usual inactive recreation and pastimes for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	3	8
H139	I am doing more inactive pastimes in place of my other usual activities	1	2	1	2	1	2	1	2	3	8
H140	I am doing fewer community activities	1	2	1	2	1	2	1	2	3	8
H141	I am cutting down on some of my usual physical recreation or activities	1	2	1	2	1	2	1	2	3	8
H142	I am not doing any of my usual physical recreation or activities	1	2	1	2	1	2	1	2	3	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H143. Please remember to answer "yes" to those statements that you are <u>sure</u> describe you today are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Do you think there is more than a 50-50 chance that this will improve after your cataract surgery?

C. **<u>IF YES:</u>** How much improvement do you expect after your cataract surgery: A little, a moderate amount, or a great deal?

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: EXPECT TO IMPROVE		(C) IF YES: IMPROVEMENT EXPECTED			
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	A LITTLE	MODERATE AMOUNT	GREAT DEAL	DONT KNOW
H144	I am eating much less than usual	1	2	1	2	1	2	1	2	3	8
H145	I feed myself but only by using specially prepared food or utensils	1	2	1	2	1	2	1	2	3	8
H146	I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar	1	2	1	2	1	2	1	2	3	8
H147	I eat no food at all but am taking fluids	1	2	1	2	1	2	1	2	3	8
H148	I just pick or nibble at my food	1	2	1	2	1	2	1	2	3	8
H149	I am drinking less fluids	1	2	1	2	1	2	1	2	3	8
H150	I feed myself with help from someone else	1	2	1	2	1	2	1	2	3	8
H151	I do not feed myself at all, but must be fed	1	2	1	2	1	2	1	2	3	8
H152	I am eating no food at all, nutrition is taken through tubes or intravenous fluids	1	2	1	2	1	2	1	2	3	8

This is the end of this section

CLOSING

This is the end of the interview. Thank you very much for taking the time to answer these questions.

I will see you again four months after your operation to see how you are doing and to find out how much your vision has changed following the removal of your cataract.

I hope everything goes well with your surgery.

TIME TAKEN FOR INTERVIEW :

TO BE COMPLETED BY INTERVIEWER AT THE END OF THE INTERVIEW.

(Please Tick as appropriate)

PW1a. _____ Patients first language is English.

PW1b._____ Patients first language, other

PW2. _____ Interview conducted at pre-op assessment clinic, in hospital

PW3. _____ Interview conducted on admission to hospital

PW4. _____ Interview conducted in hospital at some other time

PW5. _____ Interview conducted at patient's home

PW6. _____ Interview completed in a single session

PW7. _____ Interview completed in two half sessions

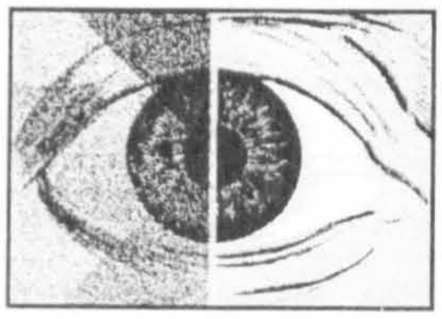
PW8. _____ Interview started, but terminated

PW9. _____ Interview not completed

PW10._____ Interview started, but failed cognitive scale

Use this space for details about cases with responses PW4, or PW7 - PW10

THE CATARACT OUTCOME STUDY



THE WELLHOUSE TRUST

4 MONTH FOLLOW-UP INTERVIEW

Patient Name: _____

Hospital Number: _____

Consultant: _____

Date of Interview: _____

Interviewer: _____

Patient ID

THE CATARACT OUTCOME STUDY
4 MONTH FOLLOW-UP INTERVIEW

INTERVIEWER: To conduct this interview you will need to know:

1. First eye operated on (Right or Left)
2. Date of 1st cataract operation
3. Date of first interview
4. Status of 2nd eye
5. Activity limitations reported at Baseline

Introduction to Patient.

Hello, my name is _____. You may remember that I am one of the Cataract Outcome Study team members from the College of Ophthalmologists and that your eye consultant is taking part in this study. It is now time for our four month follow-up interview.

In this second interview we will again ask you questions about your vision, general health, everyday activities now that you have had your first cataract operation. Again, you may refuse to answer any questions at any time during the interview.

The interview will take about 45 minutes.

Shall we begin?

Yes _____ 1
No _____ 2 Reason if any _____

COGNITIVE SCALE

IF PATIENT SEEMS TO BE CONFUSED, SEEMS UNABLE TO UNDERSTAND WHAT YOU HAVE SAID TO THEM IN THE INTRODUCTION, OR SEEMS MENTALLY UNABLE TO TAKE PART IN THE INTERVIEW, PLEASE ASK THE FOLLOWING QUESTIONS:

First, I have a few general questions.

		CORRECT	WRONG
1.	What is your full name?	1	2
2.	How old are you?	1	2
3.	When were you born?	1	2
4.	Where were you born?	1	2
5.	What is your mother's first name?	1	2
6.	What is your father's first name?	1	2
7.	Who is the Prime Minister?	1	2
8.	Who was the Prime Minister before this one?	1	2
9.	What year is this?	1	2
10.	What month is this?	1	2
11.	What day of the month is this? (What is the date?)	1	2
12.	What is the name of the city or town you are in?	1	2
13.	What day of the week is it?	1	2
14.	What time is it now?	1	2

BOX 1

IF PATIENT ANSWERS 4 OR MORE QUESTIONS INCORRECTLY, TERMINATE INTERVIEW:

Thank you very much for your help. That is all the information we need.
OTHERWISE CONTINUE.

SECTION A: GENERAL QUESTIONS ABOUT VISION

AX-1. My records show that you were scheduled to have your first cataract removed from your (1st EYE) on (DATE OF 1ST SURGERY). Was it removed then?

YES	1 (AX-6)
NO	2

AX-2 Did you have cataract surgery on your (1st EYE) since we last spoke?

YES	1
NO	2 (AX-5)

AX-3 On what date did you have the operation?

DATE / /19

AX-4 Why was the date changed?

_____

_____

_____

BOX1

IF SURGERY WAS POSTPONED AND PERFORMED LESS THAN 3 MONTHS AGO, RESCHEDULE INTERVIEW FOR FOUR MONTHS FROM FIRST SURGERY.

IF SUGERY OCCURRED 3 MONTHS AGO OR LONGER, GO TO AX-6

AX-5 Why have you not had the operation yet?

_____

_____

_____

BOX 1a

IF SURGERY WAS NOT PERFORMED TERMINATE THE INTERVIEW

AX-6 CHECK LABEL: DOES PATIENT HAVE CATARACT IN BOTH EYES?

YES	1 (AX-8)
NO	2

AX-7 Have you been told you have a cataract in your other eye since the last interview?

YES	1
NO	2 (A1)

AX-8 Have you had cataract surgery in your (OTHER EYE) since the last interview?

YES	1
NO	2 (AX-10)

AX-9 When was the cataract in that eye removed?

DATE / /19

GO TO A1

AX-10 Do you think you will have the other cataract removed?

YES	1	
NO	2	(A1)
DON'T KNOW	8	(A1)

AX-11 Do you know when you will have it removed?

YES	1	
NO	2	(A1)

AX-12 On what date is that operation planned?

DATE / /19

OR

DON'T KNOW 9-8

A1. How much trouble do you <u>now</u> have with your vision? Is it none, a little, a moderate amount, or a great deal?

NONE	1
LITTLE	2
MODERATE	3
GREAT DEAL	4

A2. How satisfied are you <u>now</u> with your vision? Are you:

Very satisfied	1
Satisfied	2
Dissatisfied or	3
Very dissatisfied?	4

AX-13 Is your vision better, worse, or about the same now as it was before you had cataract surgery?

BETTER	1	
WORSE	2	(A10)
THE SAME	3	(A10)

AX-14 How soon after surgery did you notice an improvement?

DAYS (PROBE FOR ANSWER IN "DAYS")

AX-15 How soon after surgery did you return to your usual activities?

DAYS (PROBE FOR ANSWER IN "DAYS")

A10. Do you currently <u>wear</u> glasses or contact lenses?

YES	1	(A10a)
NO	2	(A11)

A10a. Do you wear them for reading, to see things that are far away, or both? (IF PATIENT SAYS "BIFOCAL", CIRCLE BOTH)

READING	1
FAR AWAY	2
BOTH	3

A11. During the past month have you been bothered by any of the following symptoms in the eye that has had the cataract operation? (CIRCLE BELOW)

<u>IF YES:</u> ASK:

A. Are you being treated for this problem? (CIRCLE BELOW)

B. Has this improved <u>since</u> your cataract operation? (CIRCLE BELOW)

<u>IF YES</u>

C. Did this improve as much as you had expected it would <u>after</u> your cataract operation? (CIRCLE BELOW)

		(A) BOTHERED		(A) TREATMENT		(B) IMPROVED			(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED	
		YES	NO	YES	NO	YES	NO	DK	YES	NO
A12.	Red painful or tender eye	1	2	1	2	1	2	8	1	2
A13.	Feeling as if something were in your eye	1	2	1	2	1	2	8	1	2
A14.	Watery burning or itching eye	1	2	1	2	1	2	8	1	2
A15.	Double vision or distorted vision	1	2	1	2	1	2	8	1	2
A16.	A drooping eyelid	1	2	1	2	1	2	8	1	2
A17.	Spots floating before your eye	1	2	1	2	1	2	8	1	2
A18.	Glare halo or seeing rings around light	1	2	1	2	1	2	8	1	2
A19.	Blurry vision with your most recent glasses	1	2	1	2	1	2	8	1	2
A20.	Things seeming brighter than they used to in a way that is disturbing	1	2	1	2	1	2	8	1	2
A21.	Colours looking different than they used to in a way that is disturbing	1	2	1	2	1	2	8	1	2
A22.	A worsening of your vision in the eye that was operated on.	1	2	1	2	1	2	8	1	2

A23. Do you have any other eye problems, conditions, or symptoms?

YES	1	
NO	2	(A24)

A23a. What are these? (RECORD UP TO 3)

1._____

2._____

3._____

A24. Do you <u>now</u> drive a car?

YES	1 (A28)
NO	2 (A26)

A25. NOT IN THIS VERSION

A26. Did you stop driving after you had your first cataract removed?

YES, AFTER 1ST OPERATION	1
NO, STOPPED BEFORE THAT	2 (A34)
NEVER DROVE	3 (A34)

A27. Why did you stop driving?

VISION	1 (A34)
OTHER ILLNESS	2 (A34)
OTHER REASON	3 (A34)

A28. How much difficulty do you have driving during the day because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4

A29. How much difficulty do you have driving at night because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4
DO NOT DRIVE AT NIGHT	5

A30. Between (DATE OF 1ST OPERATION) and now have you been involved in any road traffic accidents while <u>you</u> were driving?

YES 1 (A31)
NO 2 (A34)

	(A)FIRST	(B) SECOND
A31. What kind of accident?	_____ _____ _____	_____ _____ _____
A32. Do you think this was because of your vision? YES NO	 1 2	 1 (A34) 2 (A34)
A33. Were there any others? YES NO	 1 (A31B) 2 (A34)	

A34. Now I'd like to ask you about injuries or accidents you may have had since your cataract operation. Between (DATE OF 1ST OPERATION) and now, have you had any injuries or accidents, such as cuts, bruises, sprains or fractures?

YES 1
NO 2(A35)

	(A)FIRST	(B) SECOND
A34a. What kind of accident? Probe for following: 1. Type of injury eg. burn 2. Site of injury eg. arm / leg 3. How injury occured eg. iron	 1_____ 2_____ 3_____	 1_____ 2_____ 3_____
A34b. Do you think this was because of your vision? YES NO	 1 2	 1 2
A34c. Were there any other accidents / injuries? YES NO	 1 2	 (A34aB)

BOX 2 RECORD "LIMITED ACTIVITIES" FROM BASELINE INTERVIEW, BELOW:
MOST IMPORTANT:
2ND MOST IMPORTANT:
3RD MOST IMPORTANT:
IF NO LIMITED ACTIVITIES REPORTED, SKIP TO A39

A35. Before your first cataract operation, you said that you were limited in doing (an activity/certain activities) because of your eyesight. Starting with the activity that you said was most important, (MOST IMPORTANT ACTIVITY), what effect has your cataract operation had on your ability to do this?

Has it had no effect	1 (BOX3)
Has it improved your ability to do (ACTIVITY), or	2 (A35a)
Has your ability to do (ACTIVITY) become worse?	3 (A35c)

A35a. Has your ability to do this improved as much as expected?

YES	1
NO	2

A35b. How soon after the operation did you notice an improvement?

DAYS _____ (PROBE FOR ANSWER IN DAYS)

A35c. Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty?	4

BOX3 IF ONLY ONE LIMITED ACTIVITY REPORTED, SKIP TO A39; OTHERWISE CONTINUE.

A36 You said that (2ND ACTIVITY) was the second most important activity that you were limited in doing. What effect has your cataract operation had on your ability to do this?

Has it had no effect	1 (BOX 4)
Has it improved your ability to do (ACTIVITY), or	2 (A36a)
Has your ability to do (ACTIVITY) become worse?	3 (A36c)

A36a Has your ability to do this improved as much as you expected?

YES	1
NO	2

A36b How soon after the operation did you notice an improvement?

DAYS _____ (PROBE FOR ANSWER IN DAYS)

A36c Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty?	4

BOX4

IF ONLY TWO LIMITED ACTIVITIES REPORTED, SKIP AS TO A39: OTHERWISE, CONTINUE

A37. You said that (3RD ACTIVITY) was the third most important activity that you were limited in doing. What effect has your cataract operation had on your ability to do this?

Has it had no effect	1 (A39)
Has it improved your ability to do (ACTIVITY), or	2 (A37a)
Has your ability to do (ACTIVITY) become worse?	3 (A37c)

A37a Has your ability to do this improved as much as you expected?

YES	1
NO	2

A37b How soon after the operation did you notice an improvement?

DAYS _____ (PROBE FOR ANSWER IN "DAYS")

A37c. Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty?	4

A38 NOT IN THIS VERSION

A39. Do you have any difficulty even with glasses in doing any of the following activities? (CIRCLE BELOW. IF PATIENT STATES S/HE DOES NOT DO THAT ACTIVITY, CIRCLE N/A FOR NOT APPLICABLE)

IF YES: ASK:

A. How much difficulty do you currently have: A little, a moderate amount, a great deal or are you unable to do (INSERT ACTIVITY)? (CIRCLE BELOW)
B. Has this improved since your cataract operation? (CIRCLE BELOW)

IF YES
C. Did this improve as much as you expected it would after your cataract operation? (CIRCLE BELOW)

		DIFFICULTY			(A) IF YES: HOW MUCH				(B) IMPROVED			(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED	
		Yes	No	N/A	A LITTLE	MODERATE AMOUNT	GREAT DEAL	UNABLE TO DO	Yes	No	DK	Yes	No
A40	Reading small print such as labels on medicine bottles,a telephone book, food labels	1	2	3	1	2	3	4	1	2	8	1	2
A41	Reading a newspaper or a book	1	2	3	1	2	3	4	1	2	8	1	2
A42	Reading a large print book print or large print newspaper or numbers on a telephone	1	2	3	1	2	3	4	1	2	8	1	2
A43	Recognizing people when they are close to you	1	2	3	1	2	3	4	1	2	8	1	2
A44	Seeing steps, stairs or kerbs	1	2	3	1	2	3	4	1	2	8	1	2
A45	Reading traffic signs, street signs, shop signs	1	2	3	1	2	3	4	1	2	8	1	2
A46	Doing fine handwork like sewing, knitting, crocheting, carpentry	1	2	3	1	2	3	4	1	2	8	1	2
A47	Writing letters, cheques, or filling out forms	1	2	3	1	2	3	4	1	2	8	1	2
A48	Playing games such as bingo, dominos, card games	1	2	3	1	2	3	4	1	2	8	1	2
A49	Taking part in sports like bowling, handball, tennis, golf	1	2	3	1	2	3	4	1	2	8	1	2
A50	Cooking	1	2	3	1	2	3	4	1	2	8	1	2
A51	Watching television	1	2	3	1	2	3	4	1	2	8	1	2
A52	Getting about indoors	1	2	3	1	2	3	4	1	2	8	1	2
A53	Getting about outdoors	1	2	3	1	2	3	4	1	2	8	1	2

SECTION B: SATISFACTION WITH CARE

Thinking about the medical care you received for your cataracts between our first interview and now from all of the doctors caring for your eyes, would you rate the following as excellent, very good, good, fair, or poor?
(CIRCLE ANSWER)

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DON'T KNOW
B1.	Attention your eye doctor(s) gave to what you had to say	1	2	3	4	5	7	8
B2.	Amount of time you had with your eye doctor(s) during a visit	1	2	3	4	5	7	8
B3.	Amount of time you had with your eye doctor(s)'staff during a visit	1	2	3	4	5	7	8
B4.	Friendliness and courtesy shown to you by your eye doctor(s)	1	2	3	4	5	7	8
B5.	Friendliness and courtesy shown to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B6.	Your eye doctor(s)' personal interest in you and your medical problems	1	2	3	4	5	7	8
B7.	Reassurance and support offered to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B8.	Consideration of your personal needs and wants in deciding <u>whether</u> to perform cataract surgery in your <u>other</u> eye	1	2	3	4	5	7	8
B9.	NOT IN THIS VERSION							
B10.	The opportunity you had to ask all the questions you wanted to about your cataracts and cataract surgery	1	2	3	4	5	7	8
B11	.The answers your doctor(s) gave to all the questions you asked about your cataract and cataract surgery	1	2	3	4	5	7	8

B12. Some doctors explain more things to patients than other doctors. We would like you to tell us whether your eye doctor(s) or anyone in their hospital explained the following things to you.
Did you receive: (CONTINUE WITH B13)

A. **FOR EACH ITEM ANSWERED YES, ASK:** Was the explanation excellent, very good, good, fair, or poor?

		YES	NO	IF YES: RATING OF EXPLANATION: EXCELL-ENT	VERY GOOD	GOOD	FAIR	POOR	DON'T KNOW
B13.	Explanations of procedures and tests performed after your first cataract operation	1	2	1	2	3	4	5	8
B14-B23	NOT IN THIS VERSION								

Thinking about the medical care you received for your cataracts between our first interview and now, including your surgery and from all of the doctors caring for your eyes, would you rate the following excellent, very good, good, fair, or poor? (CIRCLE ANSWER).

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DON'T KNOW
B24	NOT IN THIS VERSION							
B25	Convenience of the hospital location	1	2	3	4	5	7	8
B26	Hours when hospital visits can be scheduled	1	2	3	4	5	7	8
B27	How easy it was to get back and forth from your cataract surgery	1	2	3	4	5	7	8
B28	Arrangements for making appointments by phone	1	2	3	4	5	7	8
B29	Length of time you wait between making an outpatient appointment and the day of your visit.	1	2	3	4	5	7	8
B30	Length of time spent waiting at the outpatient clinic to see your eye doctor(s)	1	2	3	4	5	7	8
B31	Availability of information or advice by phone	1	2	3	4	5	7	8
B32	How easy it is for you to reach your eye doctor(s) or their nurse if you need to talk to them	1	2	3	4	5	7	8
B33	The thoroughness of the eye examination(s) since your cataract operation	1	2	3	4	5	7	8
B34	NOT IN THIS VERSION							
B35	Completeness and quality of your eye doctor(s) department and facilities	1	2	3	4	5	7	8
B36	All things considered, the care I have received for my cataract(s) has been	1	2	3	4	5	7	8
B37	Now, thinking about all the medical care that you receive, would you rate that as	1	2	3	4	5	7	8

SECTION C: GENERAL HEALTH STATUS

C1. In general, would you say your health is excellent, very good, good, fair, or poor?

EXCELLENT	1	(C1b)
VERY GOOD	2	(C1b)
GOOD	3	(C1b)
FAIR	4	(C1a)
POOR	5	(C1a)

C1a. Do you rate your health as (fair/poor) because of your vision?

YES	1	
NO	2	(C2)

C1b. Has your general health improved since your cataract operation?

YES	1	
NO	2	(C2)

C1c. Did your general health improve as much as you expected after your cataract operation?

YES	1
NO	2

C2. Compared to other people your own age, how would you rate your health? Would you say it is:

Much better,	1	(DX1)
Somewhat better,	2	(DX1)
About the same,	3	(DX1)
Somewhat worse, or	4	(C2a)
Much worse?	5	(C2a)

C2a. Do you think your health is (somewhat/much) worse than others your own age because of your vision?

YES	1
NO	2

C2b.- C34 NOT IN THIS VERSION

SECTION DX: REFERRAL AND FOLLOW-UP

DX-1 How long have you been a patient of your eye consultant?

YEARS _____
MONTHS _____

DX-2 Who referred you to (him/her)? (CIRCLE ONE)

ANOTHER OPHTHALMOLOGIST	01
OPTOMETRIST	02
OPTICIAN	03
OTHER MEDICAL DOCTOR (E.G., G.P. CARDIOLOGIST)	04
FAMILY MEMBER OF FRIEND	05
SOMEONE ELSE (SPECIFY)	06
DONT KNOW	98

DX-3 Who is taking care of your eyes now?

		YES	NO
a.	Is your Eye Consultant taking care of your eyes?	1	2
b.	Another ophthalmologist? (eye doctor)?	1	2
c.	An optometrist/optician?	1	2
d.	Your G.P.?	1	2
e	No-one	1	2

DX-4 IF R ANSWERS "NO" TO ALL ABOVE, VERIFY "NO ONE" IS CARING FOR EYES NOW.

☐ VERIFIED: NO ONE CARING FOR EYES NOW.

DX-5 Are you still under Follow-up at the Hospital?

1	YES
2	NO
9-8	DONT KNOW

DX-6 Have you been discharged from the clinic?

1	YES
2	NO
9-8	DONT KNOW

SECTION D: MEDICAL CARE

D1. Now I would like to ask you about the medical care you have received since the time of your first cataract operation until now. During this time, have you been admitted to a hospital as an <u>inpatient</u> - either for an overnight stay or for a "same day" procedure?

YES	1	
NO	2	(D2)

D1a. On how many different occasions have you been admitted to the hospital as an inpatient between (DATE OF 1ST OPERATION) and now?

NUMBER OF OCCASIONS: _____

D1b. Including all these occasions, how many nights have you spent in a hospital between (DATE OF 1ST OPERATION) and now?

NUMBER OF NIGHTS: _____

D2. Have you been a patient in a hospital casualty department between (DATE OF 1ST OPERATION) and now? (Do not count the instances in which you have been hospitalized)

YES	1	
NO	2	(D3)

D2a. How many times have you been a patient in a hospital casualty department between (DATE OF 1ST OPERATION) and now?

NUMBER OF TIMES: _____

D3. Between (DATE OF 1ST OPERATION) and now have you been an outpatient in a hospital or visited a hospital clinic? (Do not count casualty department visits or visits to eye doctor or eye clinics)

YES	1	
NO	2	(D4)

D3a. How many times have you been an outpatient or visited a hospital clinic between (DATE OF 1ST OPERATION) and now? (Do not count casualty department visits or visits to eye doctors or eye clinics)

NUMBER OF TIMES: _____

D4. Now I would like to know how many times you have seen your G.P. between (DATE OF 1ST OPERATION) and now?

NUMBER OF TIMES: _____

D5. Between (DATE OF 1ST OPERATION) and now, how many times have you seen each of the following?

a. Your eye consultant?: _____
b. An optometrist?: _____
c. Any other eye doctor?: _____
d. The doctor who did your cataract operation? _____

NOW I WOULD LIKE TO ASK YOU ABOUT THE SERVICES THAT YOU HAVE RECEIVED IN YOUR HOME.

D6. Since your cataract operation, have you received any of these ("SERVICES") in your home? _____(CIRCLE BELOW)

For each answered YES ask how many times did you use this service in the past 2 weeks?

		(A) RECEIVED (SINCE 1ST OPERATION)			(B) IF YES, HOW MANY TIMES? (Past 2 Weeks)	
	SERVICES	YES	NO	DK		DK
D7	District Nurse	1	2	8	_____	8
D8	Homecare services - home help to do cleaning / laundry	1	2	8	_____	8
D9	Assistance from relatives or friends? (Shopping, cleaning, driving)	1	2	8	_____	8
D10	Assistance with meal preparation or delivery of meals (meals on wheels)	1	2	8	_____	8
D11	Other _____	1	2	8	_____	8

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

As in the first interview, I am going to ask you a series of questions about the every day activities you do to see if there has been a change. I will start with the instructions.

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out, you may do some for shorter lengths of time, you may do some in different ways. These changes in your activities might be recent or long standing. We are interested in learning about <u>any</u> changes that describe you today and are related to your state of health.

I will be reading statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand about because they describe <u>you</u> today and are related to your state of health. As I read the questions, think of <u>yourself today</u>. I will pause briefly after each statement. When you hear one that does describe you and <u>is</u> related to health please tell me and I will check it.

Let me give you an example. I might read the statement "I am not driving my car". If this statement is related to your health and describes you today, you should tell me. Also, if you have not been driving for some time because of your health, and are still not driving today, you should answer "yes" to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not respond to it. If you simply are driving less, or are driving shorter distances, and feel that the statement only partially describes you, please do not respond to that statement as well.

Please tell me if you want me to slow down, repeat a statement, or stop so that you can think about one. Also let me know any time you would like to review the instructions. Remember we are interested in the recent or long standing changes in your activities that are related to your health.

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

H1. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H2)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H2.	I spend much of the day lying down in order to rest	1	2	1	2	1	2	1	2	8
H3.	I sit during much of the day	1	2	1	2	1	2	1	2	8
H4.	I am sleeping or dozing most of the time day and night	1	2	1	2	1	2	1	2	8
H5.	I lie down more often during the day in order to rest	1	2	1	2	1	2	1	2	8
H6.	I sit around half-asleep	1	2	1	2	1	2	1	2	8
H7.	I sleep less at night, for example,wake up too early, don't fall asleep for a long time, awaken frequently	1	2	1	2	1	2	1	2	8
H8.	I sleep or nap more during the day	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H9. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H10)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H10.	I say how bad or useless I am, for example, that I am a burden on others	1	2	1	2	1	2	1	2	8
H11.	I laugh or cry suddenly	1	2	1	2	1	2	1	2	8
H12.	I often moan and groan in pain or discomfort	1	2	1	2	1	2	1	2	8
H13.	I have attempted suicide	1	2	1	2	1	2	1	2	8
H14.	I act nervous or restless	1	2	1	2	1	2	1	2	8
H15.	I keep rubbing or holding areas of my body that hurt or are uncomfortable	1	2	1	2	1	2	1	2	8
H16.	I act irritable and impatient with myself, for example, talk badly about myself, swear at myself,blame myself for things that happen	1	2	1	2	1	2	1	2	8
H17.	I talk about the future in a hopeless way	1	2	1	2	1	2	1	2	8
H18.	I get sudden fright	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H19. Please remember to answer "yes" to those statements that you are <u>sure</u> describe you <u>today</u> and are related to your state of health. (CONTINUE WITH H20)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved <u>since</u> your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would <u>after</u> your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H20	I make difficult moves with help,for example, getting into or out of cars, bathtubs	1	2	1	2	1	2	1	2	8
H21	I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid	1	2	1	2	1	2	1	2	8
H22	I stand only for short periods of time	1	2	1	2	1	2	1	2	8
H23	I do not maintain balance	1	2	1	2	1	2	1	2	8
H24	I move my hands or fingers with some limitation or difficulty	1	2	1	2	1	2	1	2	8
H25	I stand up only with someone's help	1	2	1	2	1	2	1	2	8
H26	I kneel, stop, or bend down only by holding on to something	1	2	1	2	1	2	1	2	8
H27	I am in a restricted position all the time	1	2	1	2	1	2	1	2	8
H28	I am very clumsy in body movements	1	2	1	2	1	2	1	2	8
H29	I get in and out of bed or chairs by grasping something for support or using a stick or zimmer walking frame	1	2	1	2	1	2	1	2	8
H30	I stay lying down most of the time	1	2	1	2	1	2	1	2	8
H31	I change position frequently	1	2	1	2	1	2	1	2	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H32	I hold onto something to move myself around in bed	1	2	1	2	1	2	1	2	8
H33	I do not bathe myself completely, for example, require assistance with bathing	1	2	1	2	1	2	1	2	8
H34	I do not bathe myself at all, but am bathed by someone else	1	2	1	2	1	2	1	2	8
H35	I use bedpan with assistance	1	2	1	2	1	2	1	2	8
H36	I have trouble getting shoes, socks, or stockings on	1	2	1	2	1	2	1	2	8
H37	I do not have control of my bladder	1	2	1	2	1	2	1	2	8
H38	I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces	1	2	1	2	1	2	1	2	8
H39	I spend most of the time partly undressed or in pyjamas	1	2	1	2	1	2	1	2	8
H40	I do not have control of my bowels	1	2	1	2	1	2	1	2	8
H41	I dress myself, but do so very slowly	1	2	1	2	1	2	1	2	8
H42	I get dressed only with someone's help	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H43. Please answer "yes" to those statements that you are <u>sure</u> describe you <u>today</u> and are related to your state of health. (CONTINUE WITH H44)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved <u>since</u> your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would <u>after</u> your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	⟶ NO	↱ YES	⟶ NO	↱ YES	⟶ NO	YES	NO	DONT KNOW
H44	I do work around the house only for short periods of time or rest often	1	2	1	2	1	2	1	2	8
H45	I am doing <u>less</u> of the regular daily work around the house than I would usually do	1	2	1	2	1	2	1	2	8
H46	I am not doing <u>any</u> of the regular daily work around the house that I would usually do	1	2	1	2	1	2	1	2	8
H47	I am not doing <u>any</u> of the maintenance or repair work that I would usually do in my home or yard	1	2	1	2	1	2	1	2	8
H48	I am not doing <u>any</u> of the shopping that I would usually do	1	2	1	2	1	2	1	2	8
H49	I am not doing <u>any</u> of the house cleaning that I would usually do	1	2	1	2	1	2	1	2	8
H50	I have difficulty doing handwork, for example, turning taps, using kitchen gadgets, sewing, carpentry	1	2	1	2	1	2	1	2	8
H51	I am not doing <u>any</u> of the clothes washing that I would usually do	1	2	1	2	1	2	1	2	8
H52	I am not doing heavy work around the house	1	2	1	2	1	2	1	2	8
H53	I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H54. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H55)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H55	I am getting around only within one building	1	2	1	2	1	2	1	2	8
H56	I stay within one room	1	2	1	2	1	2	1	2	8
H57	I am staying in bed more	1	2	1	2	1	2	1	2	8
H58	I am staying in bed most of the time	1	2	1	2	1	2	1	2	8
H59	I am not now using public transportation	1	2	1	2	1	2	1	2	8
H60	I stay home most of the time	1	2	1	2	1	2	1	2	8
H61	I am only going to places with toilets nearby	1	2	1	2	1	2	1	2	8
H62	I am not going into town	1	2	1	2	1	2	1	2	8
H63	I stay away from home only for brief periods of time	1	2	1	2	1	2	1	2	8
H64	I do not get around in the dark or in unlit places without someone's help	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H65. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H66)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H66	I am going out less to visit people	1	2	1	2	1	2	1	2	8
H67	I am not going out to visit people at all	1	2	1	2	1	2	1	2	8
H68	I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help	1	2	1	2	1	2	1	2	8
H69	I often act irritable toward those around me, for example, snap at people, give sharp answers, criticise easily	1	2	1	2	1	2	1	2	8
H70	I show less affection	1	2	1	2	1	2	1	2	8
H71	I am doing fewer social activities with groups of people	1	2	1	2	1	2	1	2	8
H72	I am cutting down the length of visits with friends	1	2	1	2	1	2	1	2	8
H73	I am avoiding social visits from others	1	2	1	2	1	2	1	2	8
H74	My sexual activity is decreased	1	2	1	2	1	2	1	2	8
H75	I often express concern over what might be happening to my health	1	2	1	2	1	2	1	2	8
H76	I talk less with those around me	1	2	1	2	1	2	1	2	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H77	I make many demands, for example, insist that people do things for me, tell them how to do things	1	2	1	2	1	2	1	2	8
H78	I stay alone much of the time	1	2	1	2	1	2	1	2	8
H79	I act disagreeable to family members, for example, I act spiteful, I am stubborn	1	2	1	2	1	2	1	2	8
H80	I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them	1	2	1	2	1	2	1	2	8
H81	I isolate myself as much as I can from the rest of the family	1	2	1	2	1	2	1	2	8
H82	I am paying less attention to the children	1	2	1	2	1	2	1	2	8
H83	I refuse contact with family members, for example, turn away from them	1	2	1	2	1	2	1	2	8
H84	I am not doing the things I usually do to take care of my children or family	1	2	1	2	1	2	1	2	8
H85	I am not joking with family members as I usually do	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H86. Please answer "yes" to those statements that you are <u>sure</u> describe you <u>today</u> and are related to your state of health. (CONTINUE WITH H87)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved <u>since</u> your cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would <u>after</u> your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H87	I walk shorter distances or stop to rest often	1	2	1	2	1	2	1	2	8
H88	I do not walk up or down hills	1	2	1	2	1	2	1	2	8
H89	I use stairs only with mechanical support, for example, handrail, walking stick, crutches	1	2	1	2	1	2	1	2	8
H90	I walk up or down stairs only with assistance from someone else	1	2	1	2	1	2	1	2	8
H91	I get around in a wheelchair	1	2	1	2	1	2	1	2	8
H92	I do not walk at all	1	2	1	2	1	2	1	2	8
H93	I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg	1	2	1	2	1	2	1	2	8
H94	I walk only with help from someone	1	2	1	2	1	2	1	2	8
H95	I go up and down stairs more slowly, for example, stop often, one step at a time	1	2	1	2	1	2	1	2	8
H96	I do not use stairs at all	1	2	1	2	1	2	1	2	8
H97	I get around only by using a zimmer frame, crutches, cane, walls, or furniture	1	2	1	2	1	2	1	2	8
H98	I walk more slowly	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

SECTION G: Time Trade Off Scenario.

1. How long do you usually spend sleeping (both day and night)?

Hours _____
Minutes _____

2. If you have difficulty sleeping, how much sleep do you think you need in total, (both day and night)?

Hours _____
Minutes _____

I am going to read you a description of someone who takes an IMAGINARY cure before you answer the remaining questions.

Think of someone who has difficulty in seeing, their vision is blurred so that they cannot read bus numbers. They also have difficulty making out faces on television. Imagine that this person is given a cure that will completely restore their eyesight. The cure has just one snag, the person must spend extra time sleeping to rest their eyes. The cure has no other side effects, it is not painful or unpleasant in any way, it just requires the person to give up some time to improve their eyesight. Of course this means that they will have less time each day to do the things they enjoy, but, when they are awake, they will have perfect eyesight to do whatever they wish.

Now please forget the person in the story. We are interested in finding out about YOU and YOUR eyesight.

Please spend a little time thinking about the benefits that improved vision would bring to you.

3. What things would you be able to do if your eyesight is improved?

_____

4. Would you be prepared to give up some time to improve your eyesight?

Yes / No

If "NO" skip next question

5. How much EXTRA time would you be prepared to spend sleeping (either during the day or at night) to have perfect eyesight? (Please be as precise as possible)

Hours _____
Minutes _____

H110. Please answer "yes" to those statements that you are <u>sure</u> describe you <u>today</u> and are related to your state of health. (CONTINUE WITH H111)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved <u>since</u> your cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would <u>after</u> your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H111	I am having trouble writing or typing	1	2	1	2	1	2	1	2	8
H112	I communicate mostly by gestures, for example, moving head, pointing, sign language	1	2	1	2	1	2	1	2	8
H113	My speech is understood only by a few people who know me well	1	2	1	2	1	2	1	2	8
H114	I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly	1	2	1	2	1	2	1	2	8
H115	I don't write except to sign my name	1	2	1	2	1	2	1	2	8
H116	I carry on conversation only when very close to the other person or looking at him	1	2	1	2	1	2	1	2	8
H117	I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words	1	2	1	2	1	2	1	2	8
H118	I am understood with difficulty	1	2	1	2	1	2	1	2	8
H119	I do not speak clearly when I am under stress	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H120. The next group of statements has to do with any work you usually do other than managing your home. By this we mean anything that you regard as work that you do on a regular basis. Do you usually do work other than managing your home?

YES	1	(H124)
NO	2	

H121. Are you retired?

YES	1	
NO	2	(H134)

H122. Is your retirement related to your health?

YES	1	
NO	2	(H134)

H123. Is your retirement related to your vision?

YES	1	(H134)
NO	2	(H134)

H124. Now consider the work you do and answer "yes" to those statements that you are sure describe you today and are related to your state of health. (If today is a Saturday or Sunday or some other day that you would usually have off, please respond as if today were a working day).

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H125	I am not working at all	1	2	1	2	1	2	1	2	8
IF YOU CIRCLED YES TO THIS STATEMENT, COMPLETE ROW, THEN SKIP TO H134.										
H126	I am doing part of my job at home	1	2	1	2	1	2	1	2	8
H127	I am not accomplishing as much as usual at work	1	2	1	2	1	2	1	2	8
H128	I often act irritable toward my work associates, for example, snap at them, give sharp answers, criticise easily	1	2	1	2	1	2	1	2	8
H129	I am working shorter hours	1	2	1	2	1	2	1	2	8
H130	I am doing only light work	1	2	1	2	1	2	1	2	8
H131	I work only for short periods of time or take frequent rests	1	2	1	2	1	2	1	2	8
H132	I am working at my usual job but with some changes, for example, using different tools or special aids, trading some tasks with other workers	1	2	1	2	1	2	1	2	8
H133	I do not do my job as carefully and accurately as usual	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H134. This group of statements has to do with activities you usually do in your free time. These activities are things that you might do for relaxation, to pass the time, or for entertainment. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H135	I do my hobbies and recreation for shorter periods of time	1	2	1	2	1	2	1	2	8
H136	I am going out for entertainment less often	1	2	1	2	1	2	1	2	8
H137	I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	8
H138	I am not doing any of my usual inactive recreation and pastimes for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	8
H139	I am doing more inactive pastimes in place of my other usual activities	1	2	1	2	1	2	1	2	8
H140	I am doing fewer community activities	1	2	1	2	1	2	1	2	8
H141	I am cutting down on some of my usual physical recreation or activities	1	2	1	2	1	2	1	2	8
H142	I am not doing any of my usual physical recreation or activities	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H143. Please remember to answer "yes" to those statements that you are sure describe you today are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		⌐→ YES	⟶ NO	⌐→ YES	⟶ NO	⌐→ YES	⟶ NO	YES	NO	DONT KNOW
H144	I am eating much less than usual	1	2	1	2	1	2	1	2	8
H145	I feed myself but only by using specially prepared food or utensils	1	2	1	2	1	2	1	2	8
H146	I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar	1	2	1	2	1	2	1	2	8
H147	I eat no food at all but am taking fluids	1	2	1	2	1	2	1	2	8
H148	I just pick or nibble at my food	1	2	1	2	1	2	1	2	8
H149	I am drinking less fluids	1	2	1	2	1	2	1	2	8
H150	I feed myself with help from someone else	1	2	1	2	1	2	1	2	8
H151	I do not feed myself at all, but must be fed	1	2	1	2	1	2	1	2	8
H152	I am eating no food at all, nutrition is taken through tubes or intravenous fluids	1	2	1	2	1	2	1	2	8

This is the end of this section

CLOSING

This is the end of the interview. Thank you very much for taking the time to answer these questions. The information you have given us has been very important to this study

I will see you again in eight months time to see how you are doing. We shall contact you shortly before we are due to see you again.

TIME TAKEN FOR INTERVIEW :

TO BE COMPLETED BY INTERVIEWER AT THE END OF THE INTERVIEW.

(Please Tick as appropriate)

PW1a. _____ Patients first language is English.

PW1b._____ Patients first language, other

PW2. _____ Interview conducted in out-patient clinic, at clinical follow-up visit

PW3. _____ Interview conducted elsewhere in the hospital, at clinical follow-up visit

PW4. _____ Interview conducted in hospital at some other time

PW5. _____ Interview conducted at patient's home

PW6. _____ Interview completed in a single session

PW7. _____ Interview completed in two half sessions

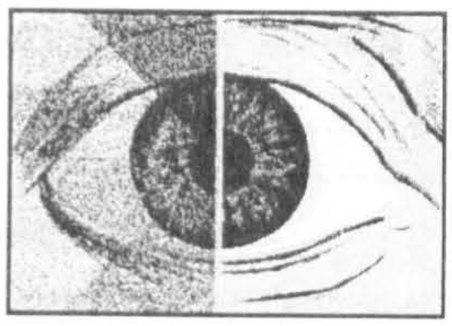
PW8. _____ Interview started, but terminated

PW9. _____ Interview not completed

PW10._____ Interview started, but failed cognitive scale

Use this space for details about cases with responses PW3-PW4, or PW7 - PW10

THE CATARACT OUTCOME STUDY



THE WELLHOUSE TRUST

12 MONTH FOLLOW-UP INTERVIEW

Patient Name: _____

Hospital Number: _____

Consultant: _____

Date of Interview: _____

Interviewer: _____

Patient ID

THE CATARACT OUTCOME STUDY
12 MONTH FOLLOW-UP INTERVIEW

INTERVIEWER: To conduct this interview you will need to know:

1. First eye operated on (Right or Left)
2. Date of 1st cataract operation
3. Status of 2nd eye at 4 month interview
4. Date of 4 month interview
5. Date of 2nd eye surgery
6. Driving status at 4 month interview
7. Activity limitations reported at Baseline

Introduction to Patient.

Hello, my name is _____. You may remember that I am one of the Cataract Outcome Study team members from the College of Ophthalmologists and that your eye consultant is taking part in this study. It is now time for our twelve month follow-up interview.

In this third interview we will again ask you questions about your vision, general health, everyday activities now that you have had your first cataract operation. Again, you may refuse to answer any questions at any time during the interview.

The interview will take about 45 minutes.

Shall we begin?

Yes _____ 1
No _____ 2 Reason if any _____

COGNITIVE SCALE

IF PATIENT SEEMS TO BE CONFUSED, SEEMS UNABLE TO UNDERSTAND WHAT YOU HAVE SAID TO THEM IN THE INTRODUCTION, OR SEEMS MENTALLY UNABLE TO TAKE PART IN THE INTERVIEW, PLEASE ASK THE FOLLOWING QUESTIONS:

First, I have a few general questions.

		CORRECT	WRONG
1.	What is your full name?	1	2
2.	How old are you?	1	2
3.	When were you born?	1	2
4.	Where were you born?	1	2
5.	What is your mother's first name?	1	2
6.	What is your father's first name?	1	2
7.	Who is the Prime Minister?	1	2
8.	Who was the Prime Minister before this one?	1	2
9.	What year is this?	1	2
10.	What month is this?	1	2
11.	What day of the month is this? (What is the date?)	1	2
12.	What is the name of the city or town you are in?	1	2
13.	What day of the week is it?	1	2
14.	What time is it now?	1	2

BOX 1

IF PATIENT ANSWERS 4 OR MORE QUESTIONS INCORRECTLY, TERMINATE INTERVIEW:

Thank you very much for your help. That is all the information we need.
OTHERWISE CONTINUE.

SECTION A: GENERAL QUESTIONS ABOUT VISION

AX-1- AX5 NOT IN THIS VERSION

AX-6 CHECK LABEL: WHAT WAS STATUS OF SECOND EYE AT TIME OF 4-MONTH INTERVIEW?

NO CATARACT IN SECOND EYE	1
CATARACT, NO SURGERY SCHEDULED	2 (AX-8)
CATARACT SCHEDULED FOR REMOVAL	3 (AX-8)
CATARACT ALREADY REMOVED	4 (AX-9)

AX-7 Since our last interview 8 months ago in (MONTH OF FOUR-MONTH INTERVIEW), have you been told you have a cataract in your other eye?

YES	1
NO	2 (A1)

AX-8 Have you had cataract surgery in your other eye since the last interview?

YES	1(AX-9A)
NO	2

AX-8A Is surgery scheduled for that eye?

YES	1
NO	2 (A1)
DONT KNOW	3 (A1)

AX-8B On what date is that operation scheduled?

DATE / /19	
OR	
DONT KNOW	9-8

GO TO A1

AX-9 My records show that you had the cataract in your (SECOND EYE) removed on (DATE OF SECOND SURGERY). Is that correct?

YES	1 (AX-9B)
NO	2
DONT KNOW	3 (AX-9B)

AX-9A When was the cataract in that eye removed?

DATE / /19

AX-9B Did your vision get better, worse or stay about the same after the second cataract was removed?

BETTER	1
WORSE	2
THE SAME	3
DONT KNOW	8

AX-10- AX12 NOT IN THIS VERSION

A1. How much trouble do you <u>now</u> have with your vision? Is it none, a little, a moderate amount, or a great deal?

NONE	1
LITTLE	2
MODERATE	3
GREAT DEAL	4

AX-13 Overall, is your vision better, worse, or about the same now as it was at our last interview 8 months ago (MONTH OF 4 MONTH INTERVIEW), that is 4 months after your first cataract operation?

BETTER	1
WORSE	2
THE SAME	3
DONT KNOW	8

AX-13A Overall, how satisfied are you now with your vision? Are you:

Very satisfied	1
Satisfied	2
Dissatisfied or	3
Very dissatisfied?	4

AX-14 Now thinking specifically about the (first) eye that was operated on, is your vision in that eye better, worse, or about the same now as it was at our last interview 8 months ago?

BETTER	1 (AX-14C)
WORSE	2
THE SAME	3 (AX14C)
DONT KNOW	8 (AX14C)

AX-14A Could you describe how your vision is worse?

_____

_____

AX-14B When did you notice a change?

_____

AX-14C How satisfied are you now with your vision in your (FIRST EYE OPERATED ON)? Are you:

Very satisfied	1
Satisfied	2
Dissatisfied or	3
Very dissatisfied?	4

AX-15, A2-A9 NOT IN THIS VERSION

A10. Do you currently <u>wear</u> glasses or contact lenses?

YES	1	(A10a)
NO	2	(A11)

A10a. Do you wear them for reading, to see things that are far away, or both? (IF PATIENT SAYS "BIFOCAL", CIRCLE BOTH)

READING	1
FAR AWAY	2
BOTH	3

A11. During the past month have you been bothered by any of the following symptoms in the (first) eye that was operated on to have your cataract removed? (CIRCLE BELOW)

IF YES: ASK:

A. How bothersome is it: Very, somewhat, not at all? (CIRCLE BELOW)

B. Are you being treated for this problem? (CIRCLE BELOW)

		BOTHERED		(A) IF YES HOW BOTHERSOME?				(B) TREAT-MENT	
		YES	NO	VERY	SOME WHAT	A LITTLE	NOT AT ALL	YES	NO
A12.	Red painful or tender eye	1	2	1	2	3	4	1	2
A13.	Feeling as if something were in your eye	1	2	1	2	3	4	1	2
A14.	Watery burning or itching eye	1	2	1	2	3	4	1	2
A15.	Double vision or distorted vision	1	2	1	2	3	4	1	2
A16.	A drooping eyelid	1	2	1	2	3	4	1	2
A17.	Spots floating before your eye	1	2	1	2	3	4	1	2
A18.	Glare halo or seeing rings around light	1	2	1	2	3	4	1	2
A19.	Blurry vision with your most recent glasses	1	2	1	2	3	4	1	2
A20.	Things seeming brighter than they used to in a way that is disturbing	1	2	1	2	3	4	1	2
A21.	Colours looking different than they used to in a way that is disturbing	1	2	1	2	3	4	1	2
A22.	A worsening of your vision in the past month in the eye having surgery	1	2	1	2	3	4	1	2

A23. Do you currently have any other eye problems, conditions, or symptoms?

YES	1	
NO	2	(A24)

A23a. What are these? (RECORD UP TO 3)

1._____

2._____

3._____

A24. CHECK INFORMATION SHEET: WHAT WAS R'S DRIVING STATUS AT TIME OF LAST INTERVIEW?

NEVER DROVE	1
WAS NOT DRIVING THEN	2 (A24B)
WAS DRIVING THEN	3 (A24D)

A24A At the time of the last interview 8 months ago, you said you had never driven a car. Have you started driving since then?

YES	1	(A28)
NO	2	(A34)

A24B At the time of the last interview 8 months ago, you said you were not driving. Are you driving a car now?

YES	1	(A28)
NO	2	

A24C Why are you not driving now? (CIRCLE ONE)

VISION	1	(A34)
OTHER ILLNESS	2	(A34)
OTHER REASON	3	(A34)

A24D. At the time of the last interview 8 months ago, you said you were driving a car, Are you still driving a car?

YES	1	(A28)
NO	2	(A25X)

A25. NOT IN THIS VERSION

A25X CHECK INFORMATION SHEET AND QUESTION AX-8: HAS R HAD SURGERY ON SECOND EYE?

YES	1	
NO	2	(A27)

A26. When did you stop driving? Was it

After your first cataract surgery but before your second surgery, or	1
After your second cataract surgery?	2

A27. Why did you stop driving?

VISION	1
OTHER ILLNESS	2
OTHER REASON	3

GO TO A30

A28. How much difficulty do you have driving during the day because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4

A28a. Has your (<u>first</u>) cataract operation made it easier for you to drive during the day?

YES	1
NO	2

A29. How much difficulty do you have driving at night because of your vision? Do you have:

No difficulty,	1
A little difficulty,	2
A moderate amount of difficulty, or	3
A great deal of difficulty?	4
DO NOT DRIVE AT NIGHT	5 (A30)

A29a Has your (first) cataract operation made it easier for you to drive at night?

YES	1
NO	2

A30. Since the last interview 8 months ago, have you been involved in any road traffic accidents while <u>you</u> were driving?

YES 1 (A31)
NO 2 (A34)
DID NOT DRIVE DURING PAST YEAR 3 (A34)

	(A)FIRST	(B) SECOND
A31. What kind of accident?	_____ _____ _____	_____ _____ _____
A32. Do you think this was because of your vision? YES NO	 1 2	 1 (A34) 2 (A34)
A33. Were there any others? YES NO	 1 (A31B) 2 (A34)	

A34. Now I'd like to ask you about injuries or accidents you may have had, since the last interview 8 months ago (MONTH OF 4-MONTH INTERVIEW), and now have you had any injuries or accidents, such as cuts, bruises, burns, sprains, fractures or falls?

YES 1
NO 2 (A35)

	(A)FIRST	(B) SECOND
A34a. What kind of accident? Probe for following: 1. Type of injury eg. burn 2. Site of injury eg. arm / leg 3. How injury occured eg. iron	 1_____ 2_____ 3_____	 1_____ 2_____ 3_____
A34b. Do you think this was because of your vision? YES NO	 1 2	 1 (BOX 1) 2 (BOX 1)
A34c. Were there any other accidents / injuries this year ? YES NO	 1 (A34aB) 2 (BOX 1)	

BOX1 RECORD "LIMITED ACTIVITIES" FROM BASELINE INTERVIEW, BELOW:
MOST IMPORTANT:
2ND MOST IMPORTANT:
3RD MOST IMPORTANT:
IF NO LIMITED ACTIVITIES REPORTED, SKIP TO A39

A35. Before your <u>first</u> cataract operation, you said that you were limited in doing (FIRST ACTIVITY) because of your eyesight. Compared to your ability (ACTIVITY) before your first cataract operation, would you say your ability to do this(ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2 (A35b)
ABOUT THE SAME	3 (A35b)
CAN'T DO FOR OTHER REASONS	6 (BOX 2)
HASN'T TRIED IT YET	7 (BOX 2)

A35a. Has your ability to do this improved as much as you expected it would as a result of the (first) cataract operation?

YES	1
NO	2

A35b. Compared to your ability to (ACTIVITY) at the time of the last interview 8 months ago, would you say your ability to (ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2
ABOUT THE SAME	3 (BOX2)

A35c. Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty, or	4
Are you unable to do it?	5

BOX 2 IF ONLY ONE LIMITED ACTIVITY REPORTED, SKIP TO A39; OTHERWISE CONTINUE.

A36 Before your <u>first</u> cataract operation, you said that you were limited in (SECOND ACTIVITY) because of your eyesight. Compared to your ability to (ACTIVITY) before your first cataract operation, would you say your ability to (ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2 (A36b)
ABOUT THE SAME	3 (A36b)
CANT DO FOR OTHER REASONS	6 (BOX 3)
HASNT TRIED IT YET	7 (BOX 3)

A36a Has your ability to do this improved as much as you expected it would as a result of the (<u>first</u>) cataract operation?

YES	1
NO	2

A36b Compared to your ability to (ACTIVITY) at the time of the last interview 8 months ago, would you say your ability to (ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2
ABOUT THE SAME	3 (BOX 3)

A36c Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty?	4
Are you unable to do it?	5

BOX 3

IF ONLY TWO LIMITED ACTIVITIES REPORTED, SKIP AS TO A39:
OTHERWISE CONTINUE

A37. Before your <u>first</u> cataract operation, you said that you were limited in (THIRD ACTIVITY) because of your eyesight. Compared to your ability to (ACTIVITY) before your first cataract operation, would you say your ability to (ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2 (A37b)
ABOUT THE SAME	3 (A37b)
CANT DO FOR OTHER REASONS	6 (A39)
HASNT TRIED IT YET	7 (A39)

A37a Has your ability to do this improved as much as you expected it would as a result of the first cataract operation?

YES	1
NO	2

A37b Compared to your ability to (ACTIVITY) at the time of the last interview 8 months ago, would you say your ability to (ACTIVITY) now is better, worse, or about the same?

BETTER	1
WORSE	2
ABOUT THE SAME	3 (A39)

A37c. Are you now able to do (ACTIVITY) with:

No difficulty	1
A little difficulty,	2
A moderate amount of difficulty,	3
A great deal of difficulty?	4
Are you unable to do it?	5

A38 NOT IN THIS VERSION

A39. Do you have any difficulty even with glasses in doing any of the following activities? (CIRCLE BELOW. IF PATIENT STATES S/HE DOES NOT DO THAT ACTIVITY, CIRCLE N/A FOR NOT APPLICABLE)

IF YES: ASK:

A. How much difficulty do you currently have: A little, a moderate amount, a great deal or are you unable to do (INSERT ACTIVITY)? (CIRCLE BELOW)

		DIFFICULTY			(A) IF YES: HOW MUCH			
		Yes	No	N/A	A LITTLE	MODERATE AMOUNT	GREAT DEAL	UNABLE TO DO
A40	Reading small print such as labels on medicine bottles,a telephone book, food labels	1	2	3	1	2	3	4
A41	Reading a newspaper or a book	1	2	3	1	2	3	4
A42	Reading a large print book print or large print newspaper or numbers on a telephone	1	2	3	1	2	3	4
A43	Recognizing people when they are close to you	1	2	3	1	2	3	4
A44	Seeing steps, stairs or kerbs	1	2	3	1	2	3	4
A45	Reading traffic signs, street signs, shop signs	1	2	3	1	2	3	4
A46	Doing fine handwork like sewing, knitting, crocheting, carpentry	1	2	3	1	2	3	4
A47	Writing letters, cheques, or filling out forms	1	2	3	1	2	3	4
A48	Playing games such as bingo, dominos, card games	1	2	3	1	2	3	4
A49	Taking part in sports like bowling, handball, tennis, golf	1	2	3	1	2	3	4
A50	Cooking	1	2	3	1	2	3	4
A51	Watching television	1	2	3	1	2	3	4
A52	Getting about indoors	1	2	3	1	2	3	4
A53	Getting about outdoors	1	2	3	1	2	3	4

SECTION BX: PHYSICIAN FOLLOWUP

BX-1 Now I'd like you to think about all the eye care you have received in the 8 months since the last interview (MONTH OF FOUR-MONTH INTERVIEW). Are you still being followed up in your Eye Consultant's Clinic for the eye that had the first operation?

YES	1 (Bx-5)
NO	2

BX-2. When did you last see (him/her)?

DATE / /19

PROBE: IF R DOESN'T KNOW MONTH, ASK HOW LONG AFTER SURGERY S/HE LAST SAW DOCTOR.

BX-3. At that time, did the eye doctor who saw you tell you that s/he no longer needed to see you?

YES	1(Box 4)
NO	2

BX-4. Why did you stop seeing your Eye Consultant?

_____

_____

GO TO BOX 4

BX-5. When did you last see (him/her)?

DATE / /19

PROBE: IF R DOESN'T KNOW MONTH, ASK HOW LONG AFTER SURGERY S/HE LAST SAW DOCTOR.

BOX 4

CHECK BX-2 OR BX-5

R LAST SAW DOCTOR BEFORE 4-MONTH INTERVIEW	1(BX-6)
R LAST SAW DOCTOR AFTER 4-MONTH INTERVIEW	2(BX-7)
R DOESN'T KNOW	3(BX-6)

BX-6. Have you seen anyone else for eye care since the last interview 8 months ago? Have you seen:

		YES	NO
a.	Another ophthalmologist?	1	2
b.	An optometrist/ optician?	1	2
c.	Your GP?	1	2

GO TO BX-8

BX-7. Have you seen anyone else for eye care since your last visit to your Eye Consultant/Eye doctor in (DATE FROM BX-2 OR BX-5)? Have you seen:

		YES	NO
a.	Another ophthalmologist?	1	2
b.	An optometrist/ optician?	1	2
c.	Your GP?	1	2

SECTION B: SATISFACTION WITH CARE

Thinking about the medical care you are receiving for your cataracts from all of the doctors caring for your eyes since the time you decided to have your cataract removed, would you rate the following as excellent, very good, good, fair, or poor?
(CIRCLE ANSWER)

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DONT KNOW
B1.	Attention your eye doctor(s) gave to what you had to say	1	2	3	4	5	7	8
B2.	Amount of time you had with your eye doctor(s) during a visit	1	2	3	4	5	7	8
B3.	Amount of time you had with your eye doctor(s)'staff during a visit	1	2	3	4	5	7	8
B4.	Friendliness and courtesy shown to you by your eye doctor(s)	1	2	3	4	5	7	8
B5.	Friendliness and courtesy shown to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B6.	Your eye doctor(s)' personal interest in you and your medical problems	1	2	3	4	5	7	8
B7.	Reassurance and support offered to you by your eye doctor(s)' staff	1	2	3	4	5	7	8
B8.	Consideration of your personal needs and wants in deciding whether to perform cataract surgery in your other eye	1	2	3	4	5	7	8
B9.	NOT IN THIS VERSION							
B10.	The opportunity you had to ask all the questions you wanted to about your cataracts and cataract surgery	1	2	3	4	5	7	8
B11	.The answers your doctor(s) gave to all the questions you asked about your cataract and cataract surgery	1	2	3	4	5	7	8

B12. Some doctors explain more things to patients than other doctors. We would like you to tell us whether your eye doctor(s) or anyone in their hospital explained the following things to you. Did you receive: (CONTINUE WITH B13)

A. **FOR EACH ITEM ANSWERED YES, ASK:** Was the explanation excellent, very good, good, fair, or poor?

				IF YES: RATING OF EXPLANATION					
		YES	NO	EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DONT KNOW
B13.	Explanations of procedures and tests performed after your first cataract operation	1	2	1	2	3	4	5	8
B13X	Explanations of any problems that may have developed since your first cataract operation	1	2	1	2	3	4	5	8
B14B 23	NOT IN THIS VERSION								

Thinking about the medical care you received for your cataracts during the last 8 months from all of the doctors caring for your eyes, would you rate the following excellent, very good, good, fair, or poor? (CIRCLE ANSWER).

		EXCELLENT	VERY GOOD	GOOD	FAIR	POOR	DOES NOT APPLY	DONT KNOW
B24	NOT IN THIS VERSION							
B25	Convenience of the hospital location	1	2	3	4	5	7	8
B26	Hours when hospital visits can be scheduled	1	2	3	4	5	7	8
B27	How easy it was to get back and forth from your cataract surgery	1	2	3	4	5	7	8
B28	Arrangements for making appointments by phone	1	2	3	4	5	7	8
B29	Length of time you wait between making an outpatient appointment and the day of your visit.	1	2	3	4	5	7	8
B30	Length of time spent waiting at the outpatient clinic to see your eye doctor(s)	1	2	3	4	5	7	8
B31	Availability of information or advice by phone	1	2	3	4	5	7	8
B32	How easy it is for you to reach your eye doctor(s) or their nurse if you need to talk to them	1	2	3	4	5	7	8
B33	The thoroughness of the eye examination(s) since your cataract operation	1	2	3	4	5	7	8
B34	NOT IN THIS VERSION							
B35	Completeness and quality of your eye doctor(s) department and facilities	1	2	3	4	5	7	8
B36	All things considered, the care I have received for my cataract(s) has been	1	2	3	4	5	7	8
B37	Now, thinking about all the medical care that you receive, would you rate that as	1	2	3	4	5	7	8

SECTION C: GENERAL HEALTH STATUS

C1. In general, would you say your health is excellent, very good, good, fair, or poor?

EXCELLENT	1	(C2)
VERY GOOD	2	(C2)
GOOD	3	(C2)
FAIR	4	(C1a)
POOR	5	(C1a)

C1a. Do you rate your health as (fair/poor) because of your vision?

YES	1	
NO	2	(C2)

C1b, C1c NOT IN THIS VERSION

C2. Compared to other people your own age, how would you rate your health? Would you say it is:

Much better,	1	(C3)
Somewhat better,	2	(C3)
About the same,	3	(C3)
Somewhat worse, or	4	(C2a)
Much worse?	5	(C2a)

C2a. Do you think your health is (somewhat/much) worse than others your own age because of your vision?

YES	1
NO	2

C2b.- C2c NOT IN THIS VERSION

C3. At the present time do you have any other health problems that you may need to see a doctor about regularly?
[Allow the patient to respond freely first, ticking off any conditions mentioned on the list below]. Then ask:

At the moment do you have any of the following conditions or symptoms?

IF YES:

A. How much does it interfere with your activities: Not at all, a little (some), or a great deal?

				(A) IF YES: How much does it interfere?		
		YES	NO	NOT AT ALL	A LITTLE	A GREAT DEAL
C4.	Stomach, bowel or intestinal trouble	1	2	1	2	3
C5.	Trouble with bladder, urine, kidneys	1	2	1	2	3
C6.	**FOR WOMEN:** Diseases of the ovaries or uterus	1	2	1	2	3
C7.	**FOR MEN:** Prostate trouble	1	2	1	2	3
C8.	Serious trouble with one or both ears or trouble with hearing	1	2	1	2	3
C9.	Frequent trouble with gums or mouth	1	2	1	2	3
C10.	Frequent foot trouble (for example, bunions, in growing toenails)	1	2	1	2	3
C11.	Frequent skin trouble (for example, eczema)	1	2	1	2	3
C12.	Anaemia (low red blood cell count)	1	2	1	2	3
C13.	Phlebitis or thrombophlebitis or blood clot in veins or arteries	1	2	1	2	3
C14.	High blood pressure or hypertension	1	2	1	2	3
C15.	Any heart trouble, hardening of arteries (arteriosclerosis) or effects of heart attack, angina	1	2	1	2	3
C16.	Effects of a stroke or cerebrovascular disease	1	2	1	2	3
C17.	Diabetes	1	2	1	2	3
C18.	Cancer or malignant tumour or growth	1	2	1	2	3
C19.	Recurring gall bladder or liver trouble	1	2	1	2	3
C20	Haemorrhoids or piles	1	2	1	2	3
C21.	Repeated attacks of sinus trouble	1	2	1	2	3
C22.	Hay fever or other allergy	1	2	1	2	3
C23.	Thyroid trouble or goitre	1	2	1	2	3

				(A) IF YES: How much does it interfere?		
		YES	NO	NOT AT ALL	A LITTLE	A GREAT DEAL
C24.	Emotional, nervous or mental problem	1	2	1	2	3
C25.	Arthritis, rheumatism, bursitis	1	2	1	2	3
C26.	Paralysis	1	2	1	2	3
C27.	Repeated trouble with back or spine	1	2	1	2	3
C28.	Trouble with circulation in arms or legs	1	2	1	2	3
C29.	Oedema or water retention	1	2	1	2	3
C30.	Effects of fractured or broken bones	1	2	1	2	3
C31.	Asthma	1	2	1	2	3
C32.	Chronic bronchitis or emphysema	1	2	1	2	3
C33.	Tuberculosis	1	2	1	2	3
C34.	Some other major problem (SPECIFY) _____	1	2	1	2	3

SECTION DX NOT IN THIS VERSION

SECTION D: MEDICAL CARE

D1. Now I would like to ask you about the medical care you have received since the last interview in (MONTH OF FOUR-MONTH INTERVIEW). During this time, have you been admitted to a hospital as an <u>inpatient</u> - either for an overnight stay or for a "same day" procedure?

YES	1	
NO	2	(D2)

D1a. On how many different occasions have you been admitted to the hospital as an inpatient between (MONTH OF FOUR-MONTH INTERVIEW) and now?

NUMBER OF OCCASIONS: _____

D1b. Including all these occasions, how many nights have you spent in a hospital between (MONTH OF FOUR-MONTH INTERVIEW) and now?

NUMBER OF NIGHTS: _____

D2. Have you been a patient in a hospital casualty department between (MONTH OF FOUR-MONTH INTERVIEW) and now? (Do not count the instances in which you have been hospitalized)

YES	1	
NO	2	(D3)

D2a. How many times have you been a patient in a hospital casualty department between (MONTH OF FOUR-MONTH INTERVIEW) and now?

NUMBER OF TIMES: _____

D3. Have you been an outpatient in a hospital or visited a hospital clinic between (MONTH OF FOUR-MONTH INTERVIEW) and now? (Do not count casualty department visits or visits to eye doctor or eye clinics)

YES	1	
NO	2	(D4)

D3a. How many times have you been an outpatient or visited a hospital clinic between (MONTH OF FOUR-MONTH INTERVIEW) and now? (Do not count casualty department visits or visits to eye doctors or eye clinics)

NUMBER OF TIMES: _____

D4. Now I would like to know how many times you have seen your G.P. between (MONTH OF FOUR-MONTH INTERVIEW) and now?

NUMBER OF TIMES: _____

D5. Between (MONTH OF FOUR-MONTH INTERVIEW) and now, how many times have you seen each of the following?

a. Your eye consultant?: _____
b. An optometrist?: _____
c. Any other eye doctor?: _____
d. The doctor who did your cataract operation?_____

NOW I WOULD LIKE TO ASK YOU ABOUT THE SERVICES THAT YOU HAVE RECEIVED IN YOUR HOME.

D6. Since our last interview 8 months ago, have you received any of these ("SERVICES") in your home? _____(CIRCLE BELOW)

For each answered YES ask how many times did you use this service in the past 2 weeks?

		(A) RECEIVED (in last 8 months)			(B) IF YES, HOW MANY TIMES? (Past 2 Weeks)	
	SERVICES	YES	NO	DK		DK
D7	District Nurse	1	2	8	_____	8
D8	Homecare services - home help to do cleaning / laundry	1	2	8	_____	8
D9	Assistance from relatives or friends? (Shopping, cleaning, driving)	1	2	8	_____	8
D10	Assistance with meal preparation or delivery of meals (meals on wheels)	1	2	8	_____	8
D11	Other _____	1	2	8	_____	8

SECTION G: Time Trade Off Scenario.

1. How long do you usually spend sleeping (both day and night)?

Hours _____
Minutes _____

2. If you have difficulty sleeping, how much sleep do you think you need in total, (both day and night)?

Hours _____
Minutes _____

I am going to read you a description of someone who takes an IMAGINARY cure before you answer the remaining questions.

Think of someone who has difficulty in seeing, their vision is blurred so that they cannot read bus numbers. They also have difficulty making out faces on television. Imagine that this person is given a cure that will completely restore their eyesight. The cure has just one snag, the person must spend extra time sleeping to rest their eyes. The cure has no other side effects, it is not painful or unpleasant in any way, it just requires the person to give up some time to improve their eyesight. Of course this means that they will have less time each day to do the things they enjoy, but, when they are awake, they will have perfect eyesight to do whatever they wish.

Now please forget the person in the story. We are interested in finding out about YOU and YOUR eyesight.

Please spend a little time thinking about the benefits that improved vision would bring to you.

3. What things would you be able to do if your eyesight is improved?

_____

4. Would you be prepared to give up some time to improve your eyesight?

Yes / No

If "NO" skip next question

5. How much EXTRA time would you be prepared to spend sleeping (either during the day or at night) to have perfect eyesight? (Please be as precise as possible)

Hours _____
Minutes _____

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

As in the last interview, I am going to ask you a series of questions about the every day activities you do to see if there has been a change. I will start with the instructions.

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out, you may do some for shorter lengths of time, you may do some in different ways. These changes in your activities might be recent or long standing. We are interested in learning about <u>any</u> changes that describe you today and are related to your state of health.

I will be reading statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand about because they describe <u>you</u> today and are related to your state of health. As I read the questions, think of <u>yourself today</u>. I will pause briefly after each statement. When you hear one that does describe you and <u>is</u> related to health please tell me and I will check it.

Let me give you an example. I might read the statement "I am not driving my car". If this statement is related to your health and describes you today, you should tell me. Also, if you have not been driving for some time because of your health, and are still not driving today, you should answer "yes" to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not respond to it. If you simply are driving less, or are driving shorter distances, and feel that the statement only partially describes you, please do not respond to that statement as well.

Please tell me if you want me to slow down, repeat a statement, or stop so that you can think about one. Also let me know any time you would like to review the instructions. Remember we are interested in the recent or long standing changes in your activities that are related to your health.

SECTION H: GENERAL HEALTH STATUS AND VISUAL HEALTH STATUS

H1. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H2)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since <u>first</u> your cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your <u>first</u> cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	⟶ NO	↱ YES	⟶ NO	↱ YES	⟶ NO	YES	NO	DON'T KNOW
H2.	I spend much of the day lying down in order to rest	1	2	1	2	1	2	1	2	8
H3.	I sit during much of the day	1	2	1	2	1	2	1	2	8
H4.	I am sleeping or dozing most of the time day and night	1	2	1	2	1	2	1	2	8
H5.	I lie down more often during the day in order to rest	1	2	1	2	1	2	1	2	8
H6.	I sit around half-asleep	1	2	1	2	1	2	1	2	8
H7.	I sleep less at night, for example,wake up too early, don't fall asleep for a long time, awaken frequently	1	2	1	2	1	2	1	2	8
H8.	I sleep or nap more during the day	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H9. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H10)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

	DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
	↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H10. I say how bad or useless I am, for example, that I am a burden on others	1	2	1	2	1	2	1	2	8
H11. I laugh or cry suddenly	1	2	1	2	1	2	1	2	8
H12. I often moan and groan in pain or discomfort	1	2	1	2	1	2	1	2	8
H13. I have attempted suicide	1	2	1	2	1	2	1	2	8
H14. I act nervous or restless	1	2	1	2	1	2	1	2	8
H15. I keep rubbing or holding areas of my body that hurt or are uncomfortable	1	2	1	2	1	2	1	2	8
H16. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself,blame myself for things that happen	1	2	1	2	1	2	1	2	8
H17. I talk about the future in a hopeless way	1	2	1	2	1	2	1	2	8
H18. I get sudden frights	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H19. Please remember to answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H20)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H20	I make difficult moves with help,for example, getting into or out of cars, bathtubs	1	2	1	2	1	2	1	2	8
H21	I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid	1	2	1	2	1	2	1	2	8
H22	I stand only for short periods of time	1	2	1	2	1	2	1	2	8
H23	I do not maintain balance	1	2	1	2	1	2	1	2	8
H24	I move my hands or fingers with some limitation or difficulty	1	2	1	2	1	2	1	2	8
H25	I stand up only with someone's help	1	2	1	2	1	2	1	2	8
H26	I kneel, stop, or bend down only by holding on to something	1	2	1	2	1	2	1	2	8
H27	I am in a restricted position all the time	1	2	1	2	1	2	1	2	8
H28	I am very clumsy in body movements	1	2	1	2	1	2	1	2	8
H29	I get in and out of bed or chairs by grasping something for support or using a stick or zimmer walking frame	1	2	1	2	1	2	1	2	8
H30	I stay lying down most of the time	1	2	1	2	1	2	1	2	8
H31	I change position frequently	1	2	1	2	1	2	1	2	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H32	I hold onto something to move myself around in bed	1	2	1	2	1	2	1	2	8
H33	I do not bathe myself completely, for example, require assistance with bathing	1	2	1	2	1	2	1	2	8
H34	I do not bathe myself at all, but am bathed by someone else	1	2	1	2	1	2	1	2	8
H35	I use bedpan with assistance	1	2	1	2	1	2	1	2	8
H36	I have trouble getting shoes, socks, or stockings on	1	2	1	2	1	2	1	2	8
H37	I do not have control of my bladder	1	2	1	2	1	2	1	2	8
H38	I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces	1	2	1	2	1	2	1	2	8
H39	I spend most of the time partly undressed or in pyjamas	1	2	1	2	1	2	1	2	8
H40	I do not have control of my bowels	1	2	1	2	1	2	1	2	8
H41	I dress myself, but do so very slowly	1	2	1	2	1	2	1	2	8
H42	I get dressed only with someone's help	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H43. Please answer "yes" to those statements that you are sure describe you today and are related to your state of health. (CONTINUE WITH H44)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES; EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H44	I do work around the house only for short periods of time or rest often	1	2	1	2	1	2	1	2	8
H45	I am doing less of the regular daily work around the house than I would usually do	1	2	1	2	1	2	1	2	8
H46	I am not doing any of the regular daily work around the house that I would usually do	1	2	1	2	1	2	1	2	8
H47	I am not doing any of the maintenance or repair work that I would usually do in my home or yard	1	2	1	2	1	2	1	2	8
H48	I am not doing any of the shopping that I would usually do	1	2	1	2	1	2	1	2	8
H49	I am not doing any of the house cleaning that I would usually do	1	2	1	2	1	2	1	2	8
H50	I have difficulty doing handwork, for example, turning taps, using kitchen gadgets, sewing, carpentry	1	2	1	2	1	2	1	2	8
H51	I am not doing any of the clothes washing that I would usually do	1	2	1	2	1	2	1	2	8
H52	I am not doing heavy work around the house	1	2	1	2	1	2	1	2	8
H53	I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H54. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H55)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **IF YES:** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **IF YES:** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H55	I am getting around only within one building	1	2	1	2	1	2	1	2	8
H56	I stay within one room	1	2	1	2	1	2	1	2	8
H57	I am staying in bed more	1	2	1	2	1	2	1	2	8
H58	I am staying in bed most of the time	1	2	1	2	1	2	1	2	8
H59	I am not now using public transportation	1	2	1	2	1	2	1	2	8
H60	I stay home most of the time	1	2	1	2	1	2	1	2	8
H61	I am only going to places with toilets nearby	1	2	1	2	1	2	1	2	8
H62	I am not going into town	1	2	1	2	1	2	1	2	8
H63	I stay away from home only for brief periods of time	1	2	1	2	1	2	1	2	8
H64	I do not get around in the dark or in unlit places without someone's help	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H65. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H66)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H66	I am going out less to visit people	1	2	1	2	1	2	1	2	8
H67	I am not going out to visit people at all	1	2	1	2	1	2	1	2	8
H68	I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help	1	2	1	2	1	2	1	2	8
H69	I often act irritable toward those around me, for example, snap at people, give sharp answers, criticise easily	1	2	1	2	1	2	1	2	8
H70	I show less affection	1	2	1	2	1	2	1	2	8
H71	I am doing fewer social activities with groups of people	1	2	1	2	1	2	1	2	8
H72	I am cutting down the length of visits with friends	1	2	1	2	1	2	1	2	8
H73	I am avoiding social visits from others	1	2	1	2	1	2	1	2	8
H74	My sexual activity is decreased	1	2	1	2	1	2	1	2	8
H75	I often express concern over what might be happening to my health	1	2	1	2	1	2	1	2	8
H76	I talk less with those around me	1	2	1	2	1	2	1	2	8

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H77	I make many demands, for example, insist that people do things for me, tell them how to do things	1	2	1	2	1	2	1	2	8
H78	I stay alone much of the time	1	2	1	2	1	2	1	2	8
H79	I act disagreeable to family members, for example, I act spiteful, I am stubborn	1	2	1	2	1	2	1	2	8
H80	I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them	1	2	1	2	1	2	1	2	8
H81	I isolate myself as much as I can from the rest of the family	1	2	1	2	1	2	1	2	8
H82	I am paying less attention to the children	1	2	1	2	1	2	1	2	8
H83	I refuse contact with family members, for example, turn away from them	1	2	1	2	1	2	1	2	8
H84	I am not doing the things I usually do to take care of my children or family	1	2	1	2	1	2	1	2	8
H85	I am not joking with family members as I usually do	1	2	1	2	1	2	1	2	8

IF R DOES NOT RESPOND TO ANY ITEM, ASK: Am I reading clearly enough and slowly enough?

H86. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H87)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H87	I walk shorter distances or stop to rest often	1	2	1	2	1	2	1	2	8
H88	I do not walk up or down hills	1	2	1	2	1	2	1	2	8
H89	I use stairs only with mechanical support, for example, handrail, walking stick, crutches	1	2	1	2	1	2	1	2	8
H90	I walk up or down stairs only with assistance from someone else	1	2	1	2	1	2	1	2	8
H91	I get around in a wheelchair	1	2	1	2	1	2	1	2	8
H92	I do not walk at all	1	2	1	2	1	2	1	2	8
H93	I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg	1	2	1	2	1	2	1	2	8
H94	I walk only with help from someone	1	2	1	2	1	2	1	2	8
H95	I go up and down stairs more slowly, for example, stop often, one step at a time	1	2	1	2	1	2	1	2	8
H96	I do not use stairs at all	1	2	1	2	1	2	1	2	8
H97	I get around only by using a zimmer frame, crutches, cane, walls, or furniture	1	2	1	2	1	2	1	2	8
H98	I walk more slowly	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H99. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H100)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	⟶ NO	↱ YES	⟶ NO	↱ YES	⟶ NO	YES	NO	DONT KNOW
H100	I am confused and start several actions at a time	1	2	1	2	1	2	1	2	8
H101	I have more minor accidents, for example, drop things, trip and fall, bump into things	1	2	1	2	1	2	1	2	8
H102	I react slowly to things that are said or done	1	2	1	2	1	2	1	2	8
H103	I do not finish things I start	1	2	1	2	1	2	1	2	8
H104	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things	1	2	1	2	1	2	1	2	8
H105	I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is	1	2	1	2	1	2	1	2	8
H106	I forget a lot, for example, things that happened recently, where I put things, appointments	1	2	1	2	1	2	1	2	8
H107	I do not keep my attention on any activity for long	1	2	1	2	1	2	1	2	8
H108	I make more mistakes than usual	1	2	1	2	1	2	1	2	8
H109	I have difficulty doing activities involving concentration and thinking	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H110. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (CONTINUE WITH H111)

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your cataract (first) operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H111	I am having trouble writing or typing	1	2	1	2	1	2	1	2	8
H112	I communicate mostly by gestures, for example, moving head, pointing, sign language	1	2	1	2	1	2	1	2	8
H113	My speech is understood only by a few people who know me well	1	2	1	2	1	2	1	2	8
H114	I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly	1	2	1	2	1	2	1	2	8
H115	I don't write except to sign my name	1	2	1	2	1	2	1	2	8
H116	I carry on conversation only when very close to the other person or looking at him	1	2	1	2	1	2	1	2	8
H117	I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words	1	2	1	2	1	2	1	2	8
H118	I am understood with difficulty	1	2	1	2	1	2	1	2	8
H119	I do not speak clearly when I am under stress	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H120. The next group of statements has to do with any work you usually do other than managing your home. By this we mean anything that you regard as work that you do on a regular basis. Do you usually do work other than managing your home?

YES	1	(H124)
NO	2	

H121. Are you retired?

YES	1	
NO	2	(H134)

H122. Is your retirement related to your health?

YES	1	
NO	2	(H134)

H123. Is your retirement related to your vision?

YES	1	
NO	2	(H134)

H124. Now consider the work you do and answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health. (If today is a Saturday or Sunday or some other day that you would usually have off, please respond as if today were a working day).

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		YES	NO	YES	NO	YES	NO	YES	NO	DONT KNOW
H125	I am not working at all	1	2	1	2	1	2	1	2	8
IF YOU CIRCLED YES TO THIS STATEMENT, COMPLETE ROW, THEN SKIP TO H134.										
H126	I am doing part of my job at home	1	2	1	2	1	2	1	2	8
H127	I am not accomplishing as much as usual at work	1	2	1	2	1	2	1	2	8
H128	I often act irritable toward my work associates, for example, snap at them, give sharp answers, criticise easily	1	2	1	2	1	2	1	2	8
H129	I am working shorter hours	1	2	1	2	1	2	1	2	8
H130	I am doing only light work	1	2	1	2	1	2	1	2	8
H131	I work only for short periods of time or take frequent rests	1	2	1	2	1	2	1	2	8
H132	I am working at my usual job but with some changes, for example, using different tools or special aids, trading some tasks with other workers	1	2	1	2	1	2	1	2	8
H133	I do not do my job as carefully and accurately as usual	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H134. This group of statements has to do with activities you usually do in your free time. These activities are things that you might do for relaxation, to pass the time, or for entertainment. Please answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		↱ YES	→ NO	↱ YES	→ NO	↱ YES	→ NO	YES	NO	DONT KNOW
H135	I do my hobbies and recreation for shorter periods of time	1	2	1	2	1	2	1	2	8
H136	I am going out for entertainment less often	1	2	1	2	1	2	1	2	8
H137	I am cutting down on <u>some</u> of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	8
H138	I am not doing <u>any</u> of my usual inactive recreation and pastimes for example, watching TV, playing cards, reading	1	2	1	2	1	2	1	2	8
H139	I am doing more inactive pastimes in place of my other usual activities	1	2	1	2	1	2	1	2	8
H140	I am doing fewer community activities	1	2	1	2	1	2	1	2	8
H141	I am cutting down on <u>some</u> of my usual physical recreation or activities	1	2	1	2	1	2	1	2	8
H142	I am not doing <u>any</u> of my usual physical recreation or activities	1	2	1	2	1	2	1	2	8

<u>IF R DOES NOT RESPOND TO ANY ITEM, ASK:</u> Am I reading clearly enough and slowly enough?

H143. Please remember to answer "yes" to those statements that you are <u>sure</u> describe you today and are related to your state of health.

FOR EACH ITEM ANSWERED YES, ASK:

A. Do you think this is because of your vision?

B. **<u>IF YES:</u>** Has this improved since your (first) cataract operation? (CIRCLE BELOW)

C. **<u>IF YES:</u>** Did this improve as much as you had expected it would after your (first) cataract operation? (CIRCLE BELOW)

		DESCRIBE YOU		(A) IF YES: BECAUSE OF YOUR VISION		(B) IF YES: IMPROVED		(C) IF YES: EXPECTED IMPROVEMENT ACHIEVED		
		⌜→ YES	⟶ NO	⌜→ YES	⟶ NO	⌜→ YES	⟶ NO	YES	NO	DONT KNOW
H144	I am eating much less than usual	1	2	1	2	1	2	1	2	8
H145	I feed myself but only by using specially prepared food or utensils	1	2	1	2	1	2	1	2	8
H146	I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar	1	2	1	2	1	2	1	2	8
H147	I eat no food at all but am taking fluids	1	2	1	2.	1	2	1	2	8
H148	I just pick or nibble at my food	1	2	1	2	1	2	1	2	8
H149	I am drinking less fluids	1	2	1	2	1	2	1	2	8
H150	I feed myself with help from someone else	1	2	1	2	1	2	1	2	8
H151	I do not feed myself at all, but must be fed	1	2	1	2	1	2	1	2	8
H152	I am eating no food at all, nutrition is taken through tubes or intravenous fluids	1	2	1	2	1	2	1	2	8

H153 **This is the end of this section**

CLOSING

This is the end of the interview. Thank you very much for taking part in the study and for taking the time to answer these questions. The information you have given us has been very important to this study

TIME TAKEN FOR INTERVIEW :

TO BE COMPLETED BY INTERVIEWER AT THE END OF THE INTERVIEW.

(Please Tick as appropriate)

PW1a. _____ Patients first language is English.

PW1b._____ Patients first language, other

PW2. _____ Interview conducted in out-patient clinic, in hospital

PW3. _____ Interview conducted elsewhere

PW4. _____ Interview conducted in hospital at some other time

PW5. _____ Interview conducted at patient's home

PW6. _____ Interview completed in a single session

PW7. _____ Interview completed in two half sessions

PW8. _____ Interview started, but terminated

PW9. _____ Interview not completed

PW10._____ Interview started, but failed cognitive scale

Use this space for details about cases with responses PW3-PW4, or PW7 - PW10

APPENDIX C

THE CATARACT OUTCOME STUDY : RESULTS

Appendix C1

Distribution of Cataract Symptom Score

Distribution of Comorbidity "Bother" Score

SYMPCAT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	.0000	24	7.1	7.1	7.1
	20.0000	71	21.1	21.1	28.2
	40.0000	97	28.8	28.8	57.0
	60.0000	91	27.0	27.0	84.0
	80.0000	43	12.8	12.8	96.7
	100.0000	11	3.3	3.3	100.0
	Total	337	100.0	100.0	

Hi-Res Chart # 4:Histogram of sympcat

Mean	45.401	Std err	1.335	Median	40.000
Std dev	24.505	Minimum	.000	Maximum	100.000

Valid cases	337	Missing cases	0

COMORBS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	.0000	27	8.0	9.0	9.0
	1.1494	26	7.7	8.7	17.7
	2.2989	34	10.1	11.3	29.0
	3.4483	28	8.3	9.3	38.3
	4.5977	22	6.5	7.3	45.7
	5.7471	12	3.6	4.0	49.7
	6.8966	18	5.3	6.0	55.7
	8.0460	19	5.6	6.3	62.0
	9.1954	16	4.7	5.3	67.3
	10.3448	19	5.6	6.3	73.7
	11.4943	12	3.6	4.0	77.7
	12.6437	15	4.5	5.0	82.7
	13.7931	8	2.4	2.7	85.3
	14.9425	7	2.1	2.3	87.7
	16.0920	7	2.1	2.3	90.0
	17.2414	7	2.1	2.3	92.3
	18.3908	3	.9	1.0	93.3
	19.5402	2	.6	.7	94.0
	20.6897	1	.3	.3	94.3
	21.8391	1	.3	.3	94.7
	22.9885	5	1.5	1.7	96.3
	24.1379	4	1.2	1.3	97.7
	25.2874	1	.3	.3	98.0
	26.4368	1	.3	.3	98.3
	27.5862	1	.3	.3	98.7
	29.8851	1	.3	.3	99.0
	31.0345	1	.3	.3	99.3
	33.3333	1	.3	.3	99.7
	39.0805	1	.3	.3	100.0
	.	37	11.0	Missing	
	Total	337	100.0	100.0	

Hi-Res Chart # 3:Histogram of comorbs

Mean	7.774	Std err	.395	Median	6.897
Std dev	6.834	Minimum	.000	Maximum	39.081

Valid cases 300 Missing cases 37

Appendix C2

Multiple Regression Models :

Determinants of Pre-operative Visual Function (VF-14)

File = vfa3.lst * * * * M U L T I P L E R E G R E S S I O N * * * *

Equation Number 1 Dependent Variable.. VFSD

Block Number 1. Method: Enter
OH COMORBS SEX SYMPCAT AGE6574 AGE75PLU BEVG3 BEVG4

Variable(s) Entered on Step Number
1.. BEVG4
2.. AGE6574
3.. SYMPCAT
4.. OH
5.. SEX
6.. COMORBS
7.. AGE75PLU
8.. BEVG3

Multiple R .61452
R Square .37764
Adjusted R Square .36053
Standard Error 17.98649

Analysis of Variance

	DF	Sum of Squares	Mean Square
Regression	8	57123.43837	7140.42980
Residual	291	94142.48481	323.51369

F = 22.07149 Signif F = .0000

* * * * M U L T I P L E R E G R E S S I O N * * * *

Equation Number 1 Dependent Variable.. VFSD

---------- Variables in the Equation ----------

Variable	B	SE B	95% Confdnce Intrvl B		Beta
OH	-1.056937	2.266471	-5.517691	3.403816	-.021957
COMORBS	-.531262	.156605	-.839484	-.223040	-.161406
SEX	-2.336677	2.204701	-6.675858	2.002503	-.050423
SYMPCAT	-.249755	.043714	-.335791	-.163720	-.272820
AGE6574	4.162401	3.681503	-3.083347	11.408149	.086706
AGE75PLU	7.699974	3.568918	.675809	14.724139	.169924
BEVG3	22.133809	3.974267	14.311857	29.955761	.454517
BEVG4	34.555559	3.825171	27.027051	42.084067	.752834
(Constant)	54.789735	6.620608	41.759389	67.820081	

---------- in ----------

Variable	T	Sig T
OH	-.466	.6413
COMORBS	-3.392	.0008
SEX	-1.060	.2901
SYMPCAT	-5.713	.0000
AGE6574	1.131	.2591
AGE75PLU	2.158	.0318
BEVG3	5.569	.0000
BEVG4	9.034	.0000
(Constant)	8.276	.0000

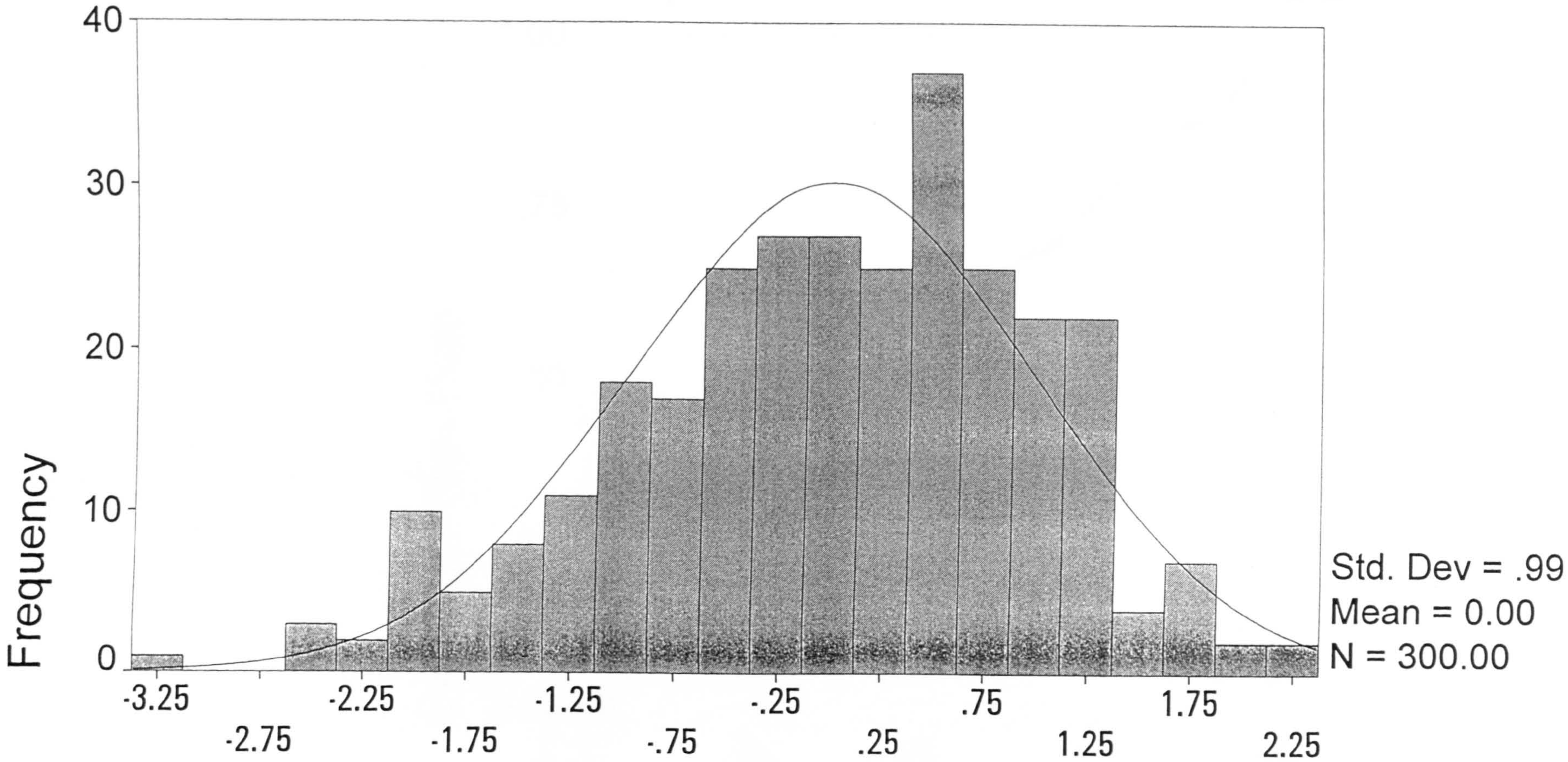
Residuals Statistics:

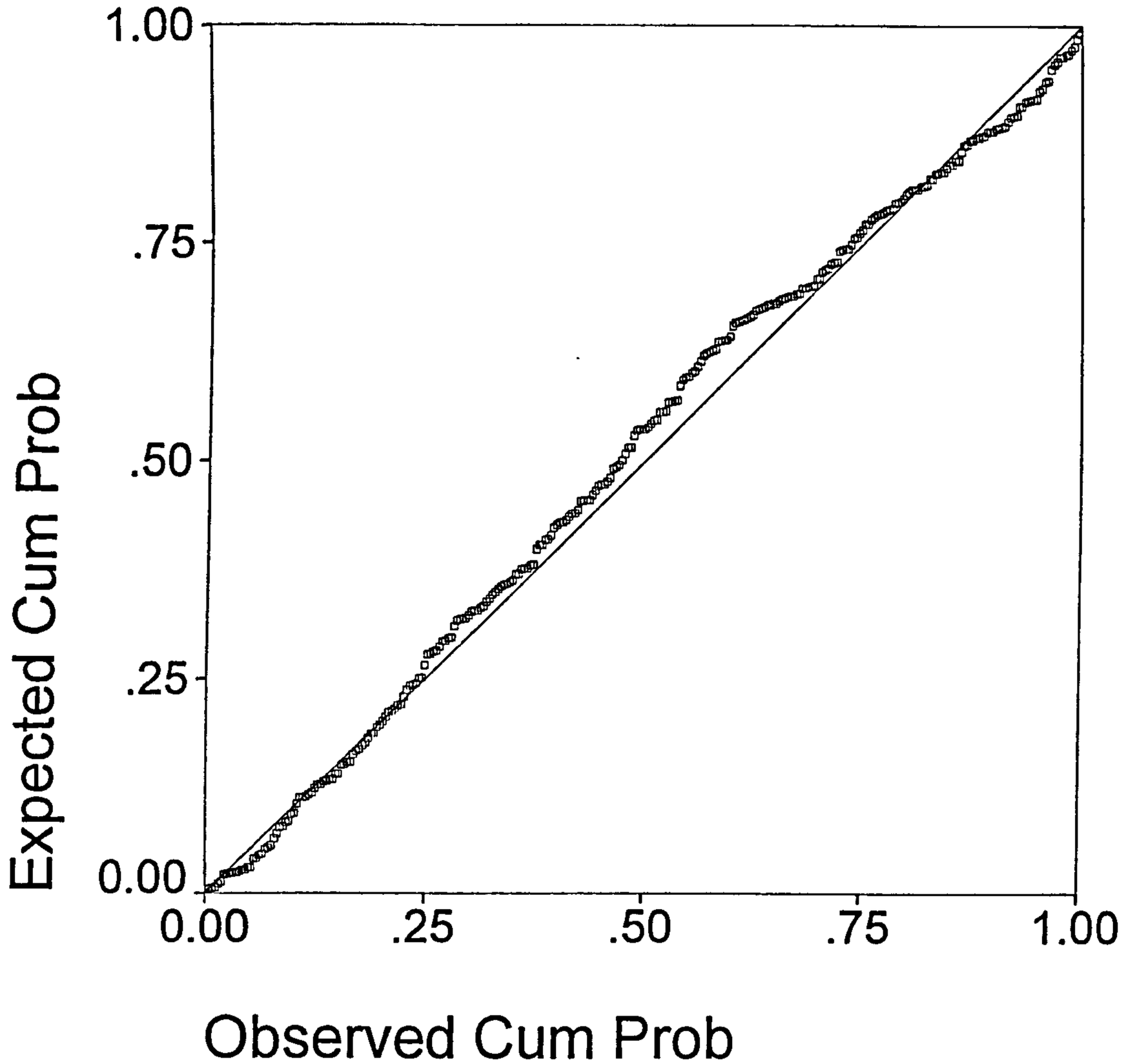
	Min	Max	Mean	Std Dev	N
*PRED	22.7505	92.3719	68.6014	13.8220	300
*RESID	-56.8512	42.5739	.0000	17.7442	300
*ZPRED	-3.3172	1.7198	.0000	1.0000	300
*ZRESID	-3.1608	2.3670	.0000	.9865	300

Total Cases = 337
Durbin-Watson Test = 1.93337

Histogram

Dependent Variable: VFSD




Normal P-P Plot of Regression Standar
Dependent Variable: VFSD
Expected Cum Prob
Observed Cum Prob
1.00
.75
.50
.25
0.00
0.00
.25
.50
.75
1.00

vfa3.sav
SEARCH FOR INTERACTIONS - VFSD AND OTHER PRE-OPERATIVE VARIABLES

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *
General Factorial Model
304 cases accepted.
0 cases rejected because of out-of-range factor values.
33 cases rejected because of missing data.
12 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFSD

Cochrans C(24,12) = .16046, P = .030 (approx.)
Bartlett-Box F(11,11011) = .71059, P = .730

- -

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Tests of Significance for VFSD using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	101748.31	291	349.65		
REGRESSION	45091.26	1	45091.26	128.96	.000
AGEG3	2246.47	2	1123.24	3.21	.042
SEX	976.04	1	976.04	2.79	.096
OH	89.70	1	89.70	.26	.613
AGEG3 BY SEX	1602.04	2	801.02	2.29	.103
AGEG3 BY OH	827.40	2	413.70	1.18	.308
SEX BY OH	.37	1	.37	.00	.974
AGEG3 BY SEX BY OH	19.30	2	9.65	.03	.973
(Model)	52364.06	12	4363.67	12.48	.000
(Total)	154112.36	303	508.62		

R-Squared = .340
Adjusted R-Squared = .313

- -

Estimates for VFSD adjusted for 1 covariate
--- Individual univariate .9500 confidence intervals

AGEG3

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
2	-5.1982935	2.64179	-1.96771	.05005	-10.39774	.00115
3	.700027688	1.99425	.35102	.72583	-3.22496	4.62502

SEX

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
4	2.57294954	1.53998	1.67077	.09584	-.45796	5.60386

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
5	-.78098963	1.54193	-.50650	.61289	-3.81573	2.25375

AGEG3 BY SEX

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
6	5.56760459	2.63017	2.11683	.03512	.39105	10.74416
7	-3.5402935	1.99370	-1.77574	.07682	-7.46420	.38361

AGEG3 BY OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
8	-2.0740689	2.62939	-.78880	.43087	-7.24910	3.10096
9	-.61812128	1.99479	-.30987	.75688	-4.54417	3.30793

SEX BY OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
10	.049617475	1.53281	.03237	.97420	-2.96719	3.06643

AGEG3 BY SEX BY OH

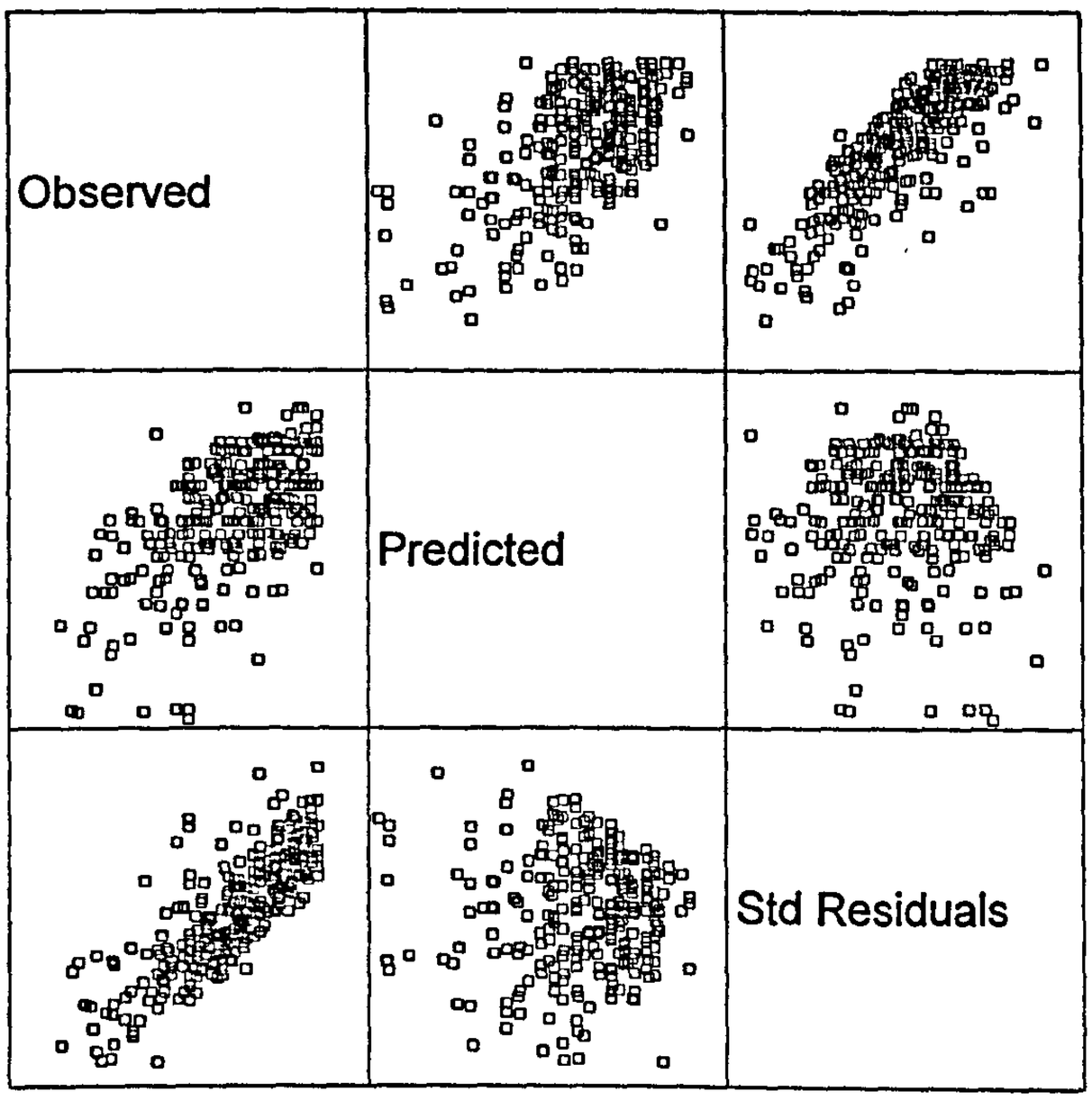
Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
11	.047041162	2.64247	.01780	.98581	-5.15373	5.24781
12	-.34203575	1.99475	-.17147	.86397	-4.26800	3.58393

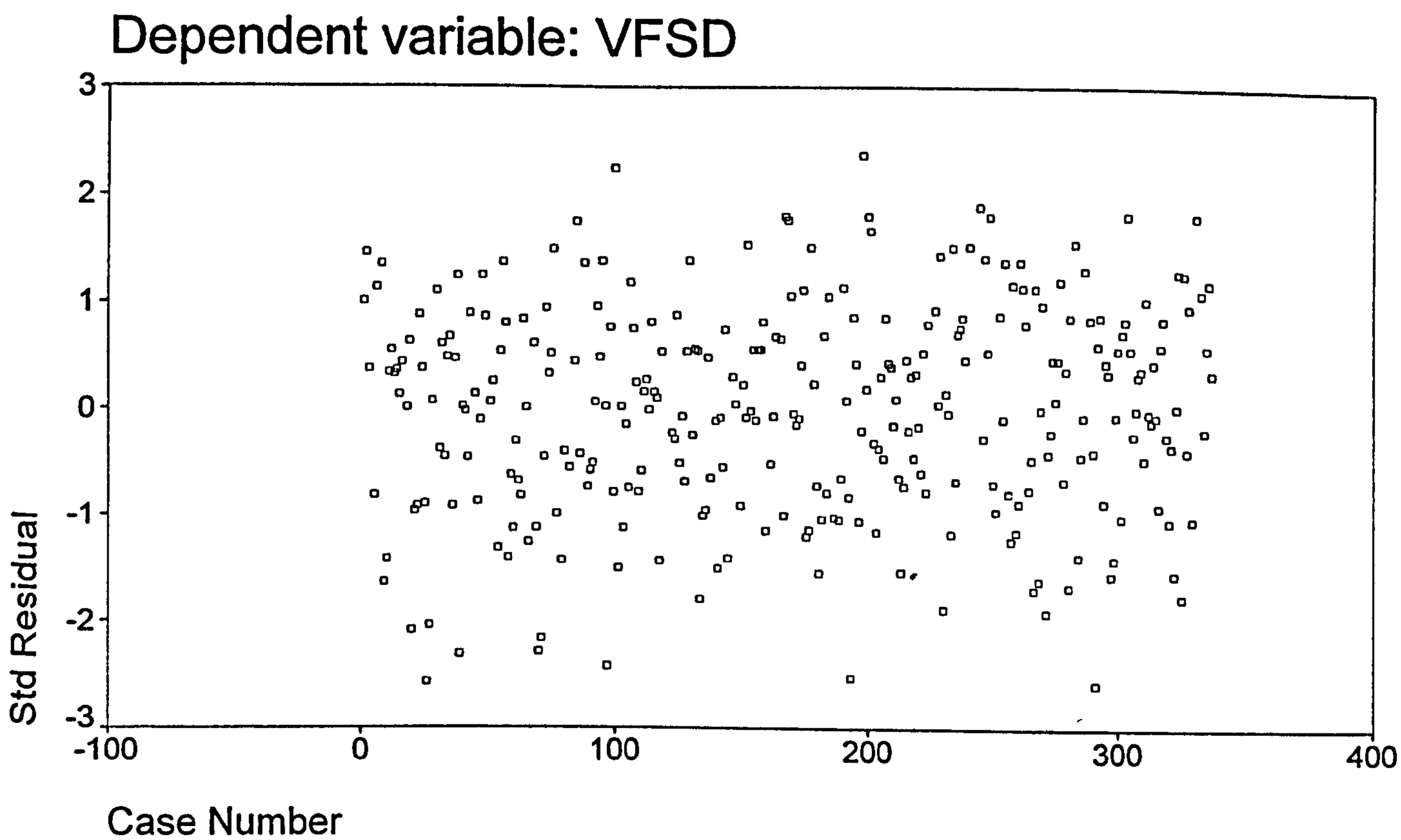
****

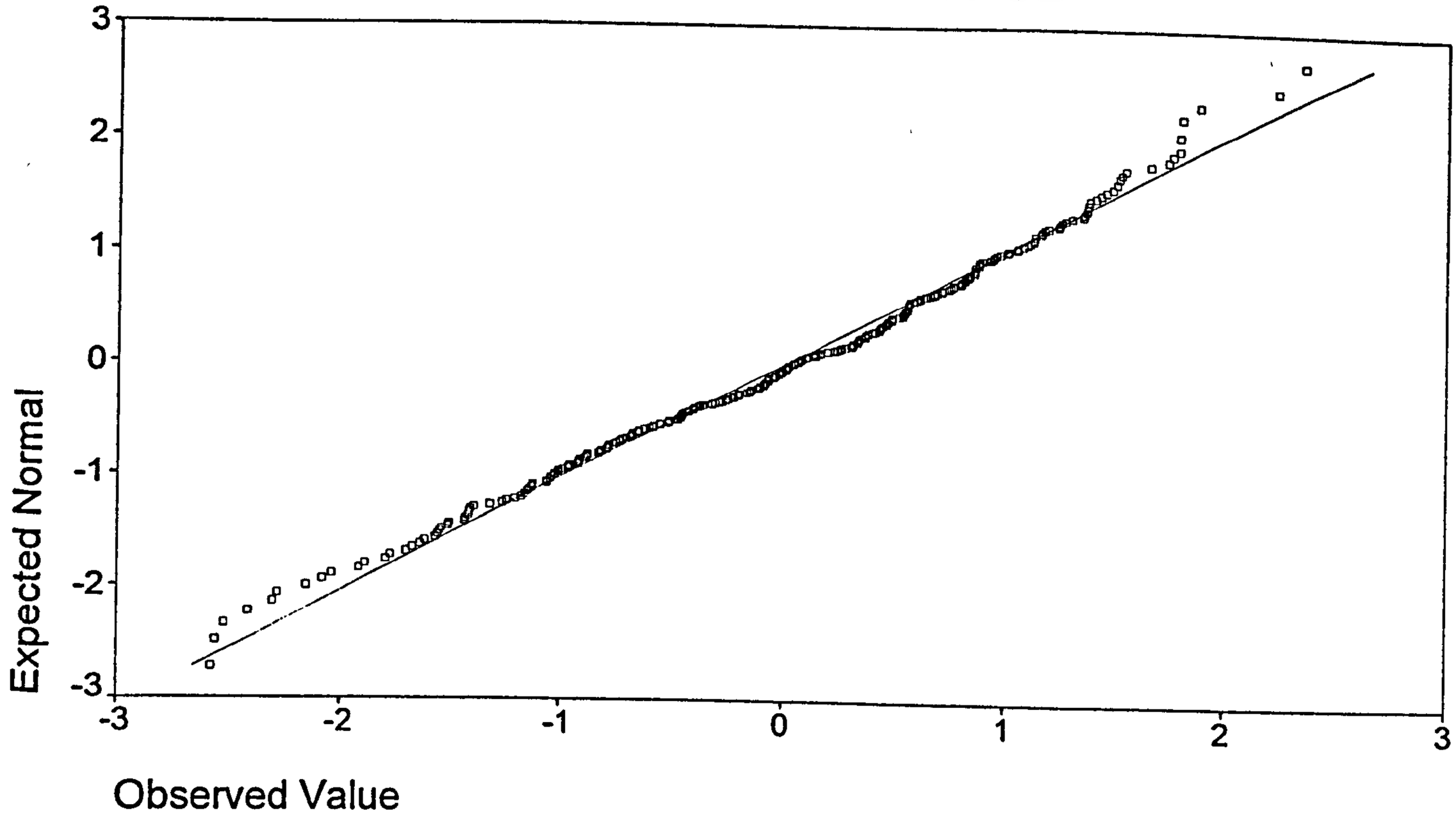
COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
BEV	7.85280	.56712	.692	11.356	.000

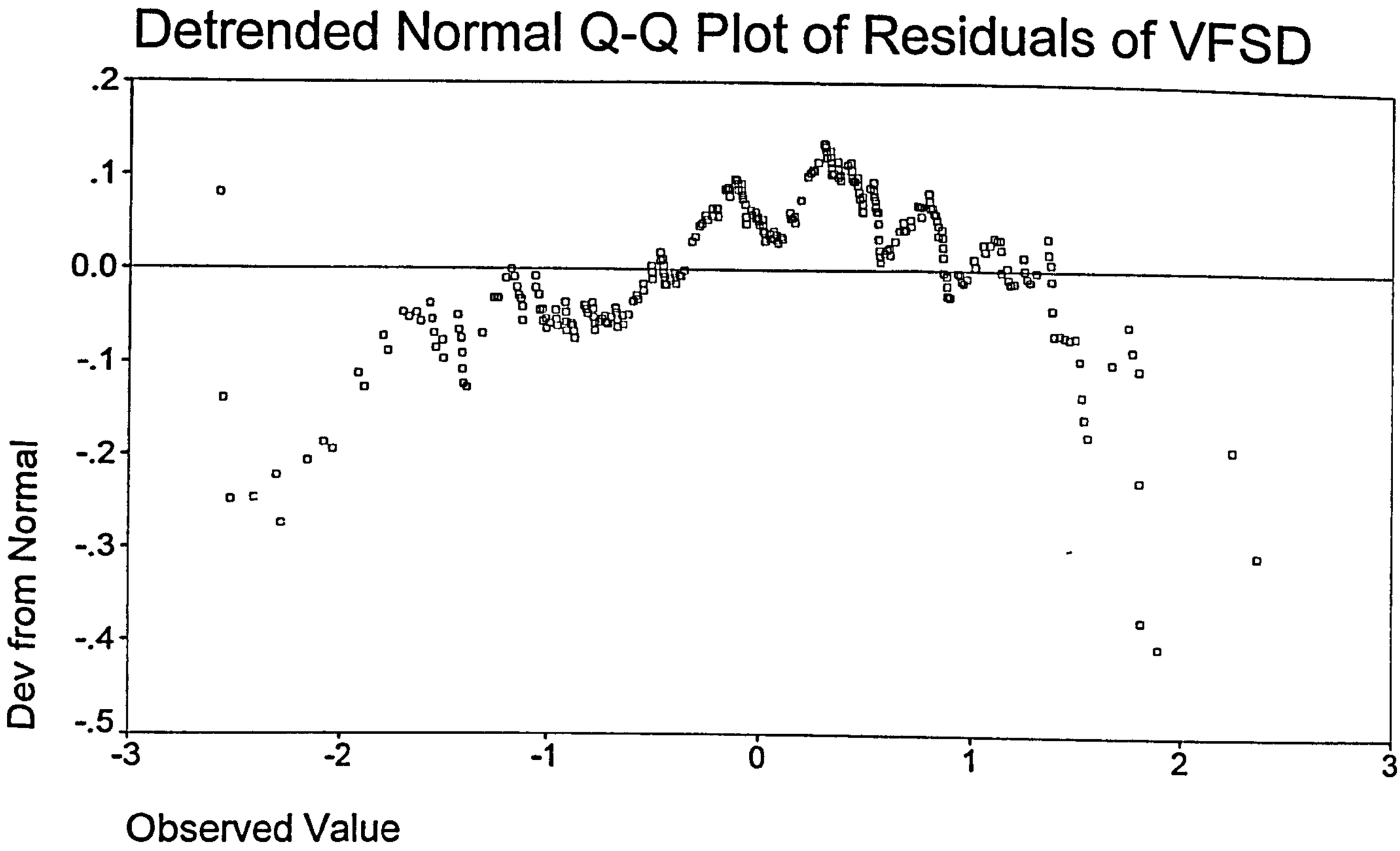
COVARIATE	Lower -95%	CL- Upper
BEV	6.492	9.214

Dependent variable: VFSD




Dependent variable: VFSD
3
2
1
0
-1
-2
-3
Std Residual
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFSD
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-3
-2
-1
0
1
2
3


Detrended Normal Q-Q Plot of Residuals of VFSD
Dev from Normal
.2
.1
0.0
-.1
-.2
-.3
-.4
-.5
-3
-2
-1
0
1
2
3
Observed Value

* * * * M U L T I P L E R E G R E S S I O N * * * *

Equation Number 1 Dependent Variable.. AGE

Block Number 1. Method: Enter
OH COMORBS SEX SYMPCAT BEVG3 BEVG4 VFSD

Variable(s) Entered on Step Number
1.. VFSD
2.. OH
3.. SEX
4.. BEVG3
5.. COMORBS
6.. SYMPCAT
7.. BEVG4

Multiple R	.40615
R Square	.16496
Adjusted R Square	.14494
Standard Error	7.63983

Analysis of Variance

	DF	Sum of Squares	Mean Square
Regression	7	3366.72689	480.96098
Residual	292	17043.15311	58.36696

F = 8.24029 Signif F = .0000

* * * * M U L T I P L E R E G R E S S I O N * * * *

Equation Number 1 Dependent Variable.. AGE

---------- Variables in the Equation ----------

Variable	B	SE B	95% Confdnce Intrvl B		Beta
OH	1.808500	.959016	-.078961	3.695961	.102279
COMORBS	.144306	.067153	.012140	.276472	.119356
SEX	2.405556	.930483	.574253	4.236859	.141317
SYMPCAT	-.052254	.019402	-.090438	-.014069	-.155392
BEVG3	-3.547219	1.764772	-7.020505	-.073933	-.198305
BEVG4	-7.602648	1.807584	-11.160193	-4.045102	-.450917
VFSD	.055461	.024665	.006917	.104005	.150987
(Constant)	73.602847	2.872181	67.950046	79.255648	

---------- in ----------

Variable	T	Sig T
OH	1.886	.0603
COMORBS	2.149	.0325
SEX	2.585	.0102
SYMPCAT	-2.693	.0075
BEVG3	-2.010	.0453
BEVG4	-4.206	.0000
VFSD	2.249	.0253
(Constant)	25.626	.0000

Equation Number 1 Dependent Variable.. AGE

Residuals Statistics:

	Min	Max	Mean	Std Dev	N
*PRED	67.9722	83.7346	74.9800	3.3556	300
*RESID	-24.3823	16.4338	.0000	7.5499	300
*ZPRED	-2.0884	2.6090	.0000	1.0000	300
*ZRESID	-3.1915	2.1511	.0000	.9882	300

Total Cases = 337

Durbin-Watson Test = 1.97947

Appendix C3

Multiple Regression Models :

Determinants of Pre-operative Quality of Life (SIP)

vffu-5a.sav Determinants of Pre-operative SIP score

**** MULTIPLE REGRESSION ****

Listwise Deletion of Missing Data

N of Cases = 249

Correlation, 1-tailed Sig:

	TOTAL	AGE	COMORBS	VFSD
TOTAL	1.000	.282	.604	-.394
	.	.000	.000	.000
AGE	.282	1.000	.152	.018
	.000	.	.008	.389
COMORBS	.604	.152	1.000	-.216
	.000	.008	.	.000
VFSD	-.394	.018	-.216	1.000
	.000	.389	.000	.

Equation Number 1 Dependent Variable.. TOTAL
Block Number 1. Method: Enter AGE COMORBS VFSD

Variable(s) Entered on Step Number
1.. VFSD
2.. AGE
3.. COMORBS

Multiple R .69281
R Square .47999
Adjusted R Square .47362
Standard Error 6.79405

Analysis of Variance

	DF	Sum of Squares	Mean Square
Regression	3	10438.49754	3479.49918
Residual	245	11308.99395	46.15916

F = 75.38047 Signif F = .0000

---------- Variables in the Equation ----------

Variable	B	SE B	95% Confdnce Intrvl B		Beta
AGE	.239700	.053423	.134473	.344927	.209435
COMORBS	.692612	.064965	.564650	.820574	.509605
VFSD	-.119995	.019709	-.158815	-.081175	-.287687
(Constant)	-3.371818	4.162896	-11.571449	4.827812	

---------- in ----------

Variable	T	Sig T
AGE	4.487	.0000
COMORBS	10.661	.0000
VFSD	-6.088	.0000
(Constant)	-.810	.4187

End Block Number 1 All requested variables entered.

Residuals Statistics:

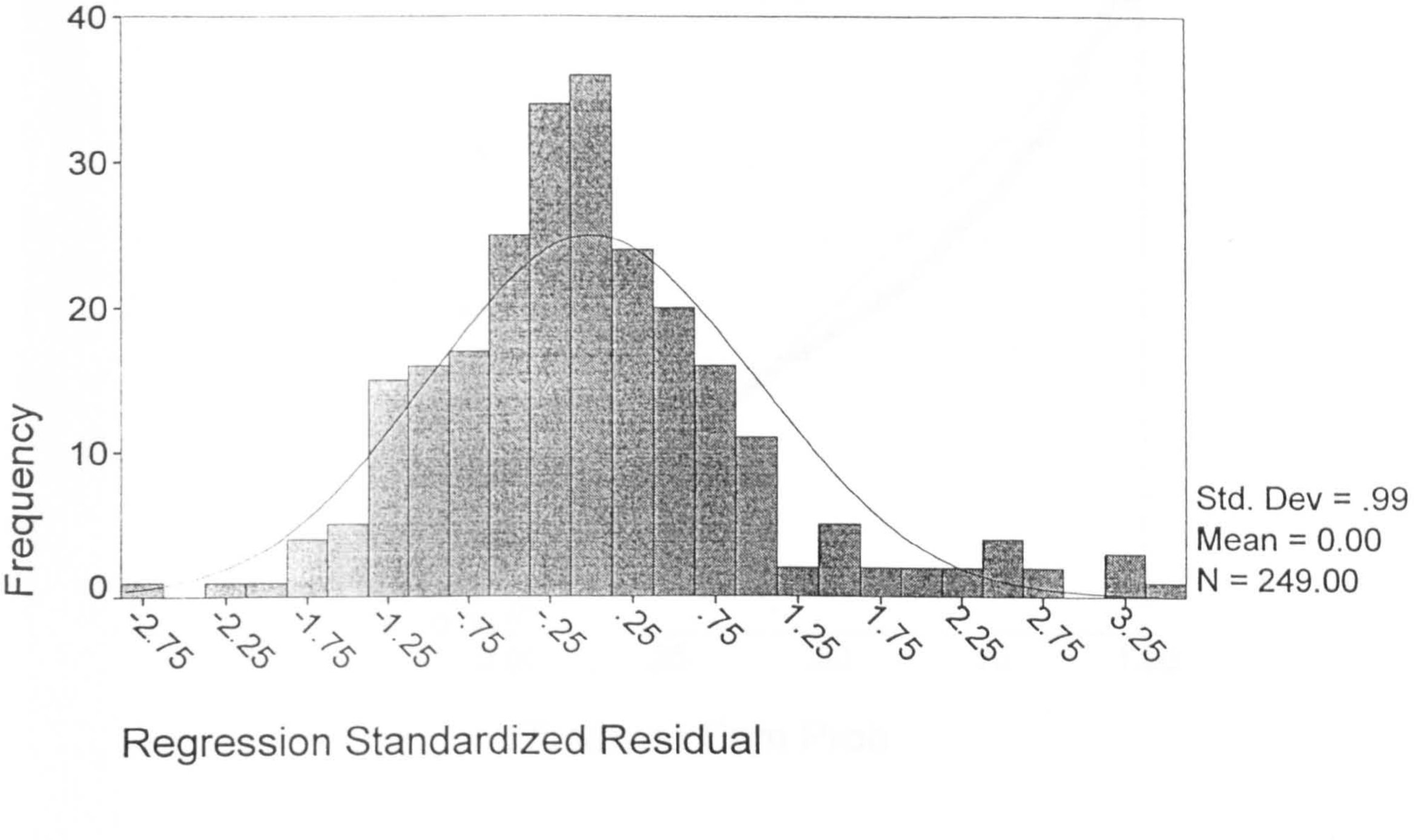
	Min	Max	Mean	Std Dev	N
*PRED	-2.5681	32.8825	11.5544	6.4877	249
*RESID	-18.9678	24.0025	.0000	6.7528	249
*ZPRED	-2.1768	3.2875	.0000	1.0000	249
*ZRESID	-2.7918	3.5329	.0000	.9939	249

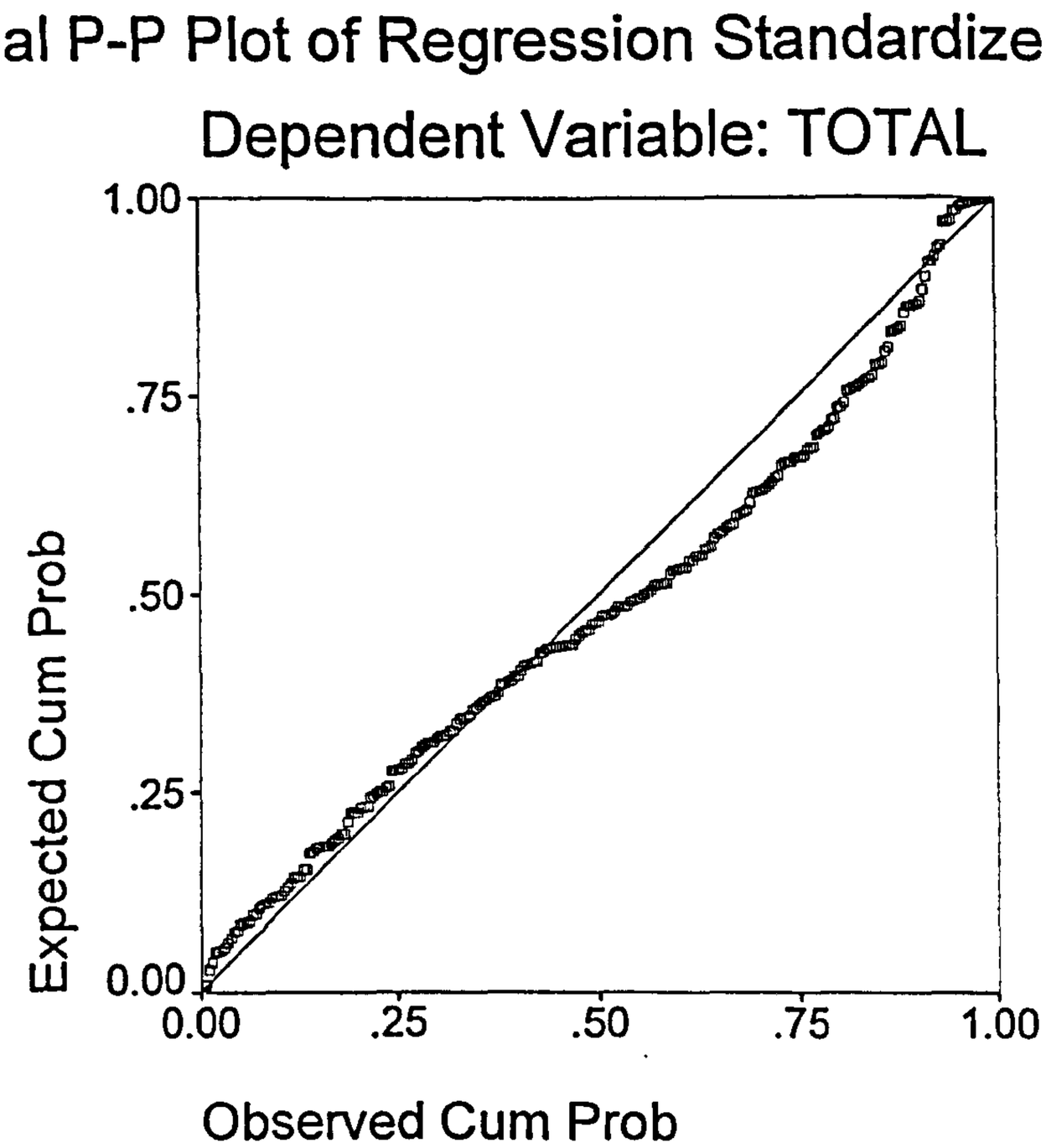
Total Cases = 337

Hi-Res Chart # 27:Histogram of *zresid
Hi-Res Chart # 28:Normal p-p plot of *zresid

Histogram

Dependent Variable: TOTAL




Normal P-P Plot of Regression Standardized Residual
Dependent Variable: TOTAL
Expected Cum Prob
Observed Cum Prob
1.00
.75
.50
.25
0.00
0.00
.25
.50
.75
1.00

Appendix C4

Multiple Regression Models :

Determinants of Pre-operative Vision-Related Quality of Life (VR-SIP)

vffu-5a.sav Determinants of Pre-operative VR-SIP score

* * * * M U L T I P L E R E G R E S S I O N * * * *

Listwise Deletion of Missing Data
N of Cases = 250

Correlation, 1-tailed Sig:

	VTOTAL	AGE	VFSD	BVHI
VTOTAL	1.000	-.085	-.636	-.380
	.	.091	.000	.000
AGE	-.085	1.000	.010	-.277
	.091	.	.436	.000
VFSD	-.636	.010	1.000	.558
	.000	.436	.	.000
BVHI	-.380	-.277	.558	1.000
	.000	.000	.000	.

Block Number 1. Method: Enter AGE VFSD BVHI
Variable(s) Entered on Step Number
1.. BVHI
2.. AGE
3.. VFSD

Multiple R	.64318
R Square	.41368
Adjusted R Square	.40653
Standard Error	2.63773

Analysis of Variance

	DF	Sum of Squares	Mean Square
Regression	3	1207.61366	402.53789
Residual	246	1711.57103	6.95761

F = 57.85581 Signif F = .0000

---------- Variables in the Equation ----------

Variable	B	SE B	95% Confdnce Intrvl B		Beta
AGE	-.041765	.021728	-.084562	.001032	-.099807
VFSD	-.089748	.009128	-.107727	-.071770	-.591434
BVHI	-.158742	.128658	-.412154	.094670	-.077227
(Constant)	12.790975	2.157722	8.541009	17.040941	

---------- in ----------

Variable	T	Sig T
AGE	-1.922	.0557
VFSD	-9.832	.0000
BVHI	-1.234	.2184
(Constant)	5.928	.0000

End Block Number 1 All requested variables entered.

Residuals Statistics:

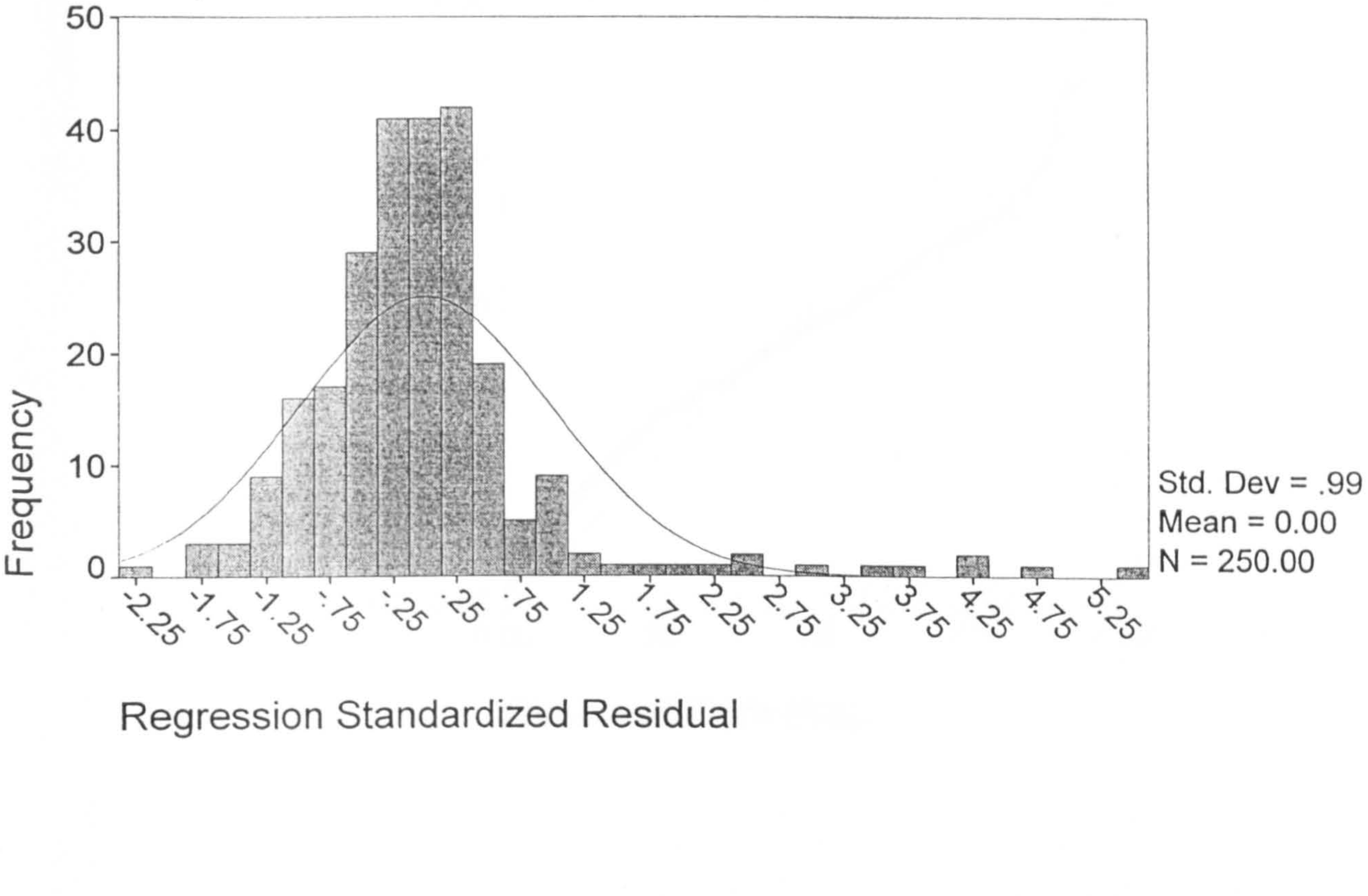
	Min	Max	Mean	Std Dev	N
*PRED	-1.4967	8.7144	1.9172	2.2022	250
*RESID	-5.9214	14.8193	.0000	2.6218	250
*ZPRED	-1.5502	3.0865	.0000	1.0000	250
*ZRESID	-2.2449	5.6182	.0000	.9940	250

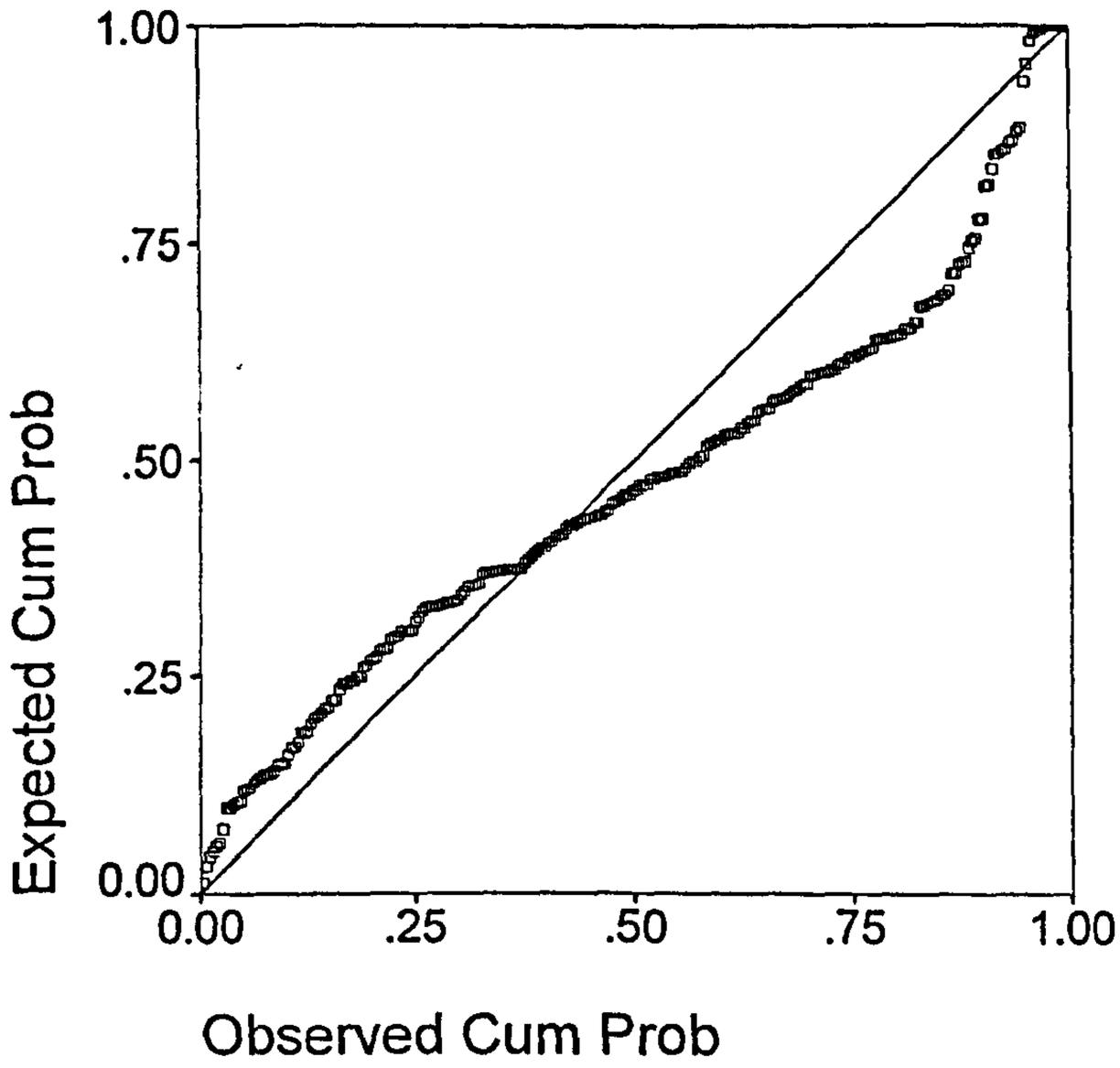
Total Cases = 337

Hi-Res Chart # 29:Histogram of *zresid
Hi-Res Chart # 30:Normal p-p plot of *zresid

Histogram

Dependent Variable: VTOTAL




Normal P-P Plot of Regression Standardized Residual
Dependent Variable: VTOTAL
Expected Cum Prob
Observed Cum Prob
0.00
.25
.50
.75
1.00

APPENDIX D

THE CATARACT OUTCOME STUDY : RELATIONSHIPS AFTER SURGERY

Appendix D1 - Analysis of Covariance Models : Determinants of Change in Visual Function at 4 Months

Appendix D2 - Analysis of Covariance Models : Determinants of Change in Visual Function at 12 Months

Appendix D3 - Analysis of Covariance Models : Determinants of Change in Visual Function at 4 Months Adjusting for pre-operative factors (capacity for change)

- model 1
- model 2

Appendix D4 - Analysis of Covariance Models : Determinants of Change in Visual Function at 12 Months Adjusting for pre-operative factors (capacity for change)

- model 1
- model 2

Appendix D1

Analysis of Covariance Models :

Determinants of Change in Visual Function at 4 Months

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL A

CHANGE IN VF-14 SCORE AND PRE-OP BETTER EYE VISUAL ACUITY 4 MONTHS

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

272 cases accepted.
0 cases rejected because of out-of-range factor values.
18 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH4M

Cochrans C(135,2) = .51300, P = .763 (approx.)
Bartlett-Box F(1,146464) = .07847, P = .779

- -

Combined Observed Means for OH
Variable .. VFCH4M

OH		
0	WGT.	19.53753
	UNWGT.	19.53753
1	WGT.	20.51897
	UNWGT.	20.51897

- -

Variable .. BVHI

OH		
0	WGT.	9.87701
	UNWGT.	9.87701
1	WGT.	9.17647
	UNWGT.	9.17647

- -

Variable .. AGE

OH		
0	WGT.	73.75401
	UNWGT.	73.75401
1	WGT.	76.69412
	UNWGT.	76.69412

- -

Tests of Significance for VFCH4M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	108671.35	268	405.49		
REGRESSION	12363.95	2	6181.97	15.25	.000
OH	28.12	1	28.12	.07	.793
(Model)	12420.23	3	4140.08	10.21	.000
(Total)	121091.58	271	446.83		

R-Squared = .103
Adjusted R-Squared = .093

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE	
VARIABLE	BVHI	AGE
VFCH4M	-.858	-.224

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
BVHI	.736
AGE	.050

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.102
OH	.000

- -

Estimates for VFCH4M adjusted for 2 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	.356076723	1.35226	.26332	.79251	-2.30633	3.01849

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH4M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
BVHI	-4.24801	-.33010	.792	-5.363	.000
AGE	-.43614	-.17018	.157	-2.781	.006

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
BVHI	-5.808	-2.688	.097
AGE	-.745	-.127	.028

- -

Adjusted and Estimated Means
Variable .. VFCH4M

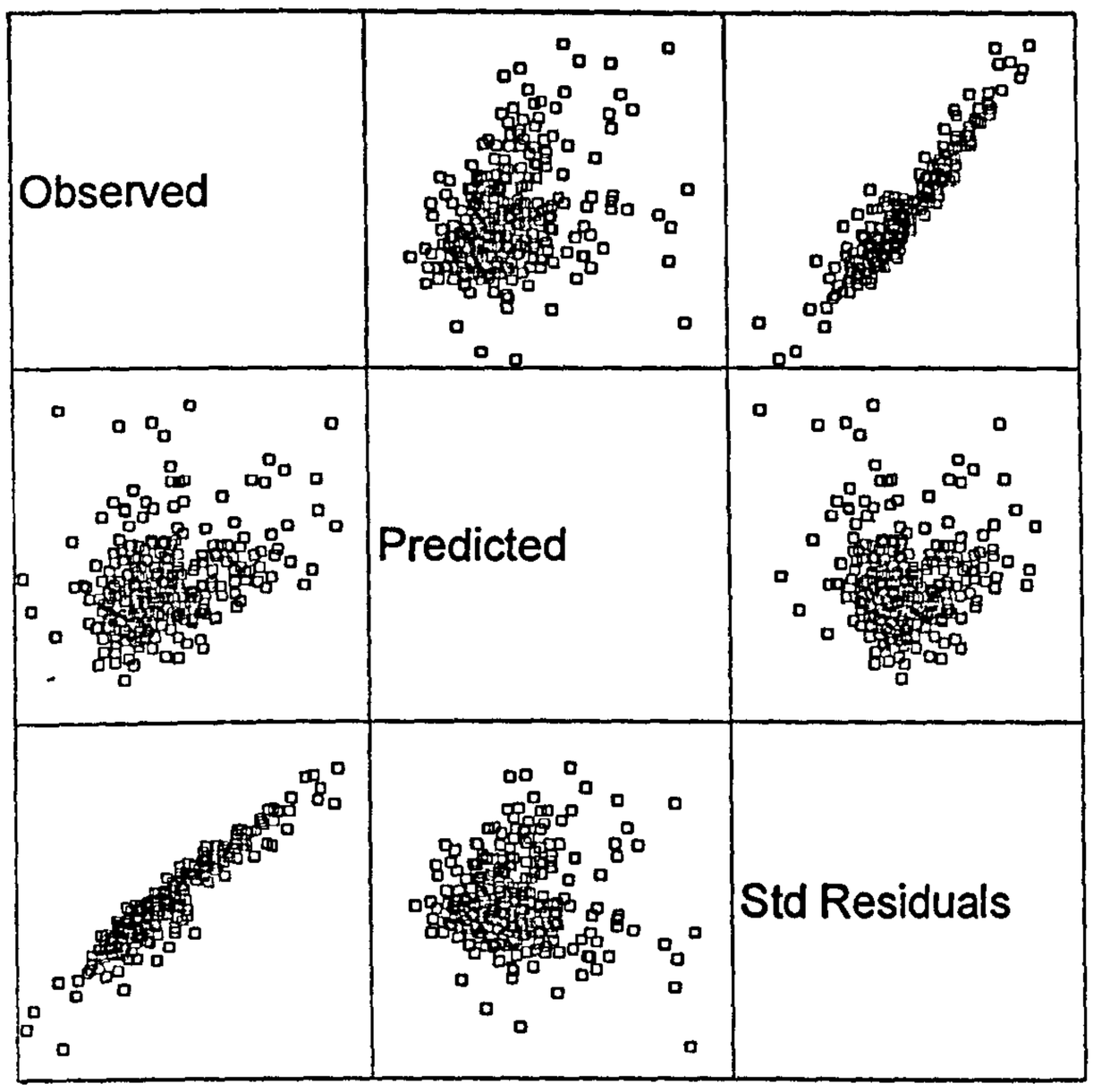
CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	19.538	20.384	19.538	.000	.000
2	20.519	19.672	20.519	.000	.000

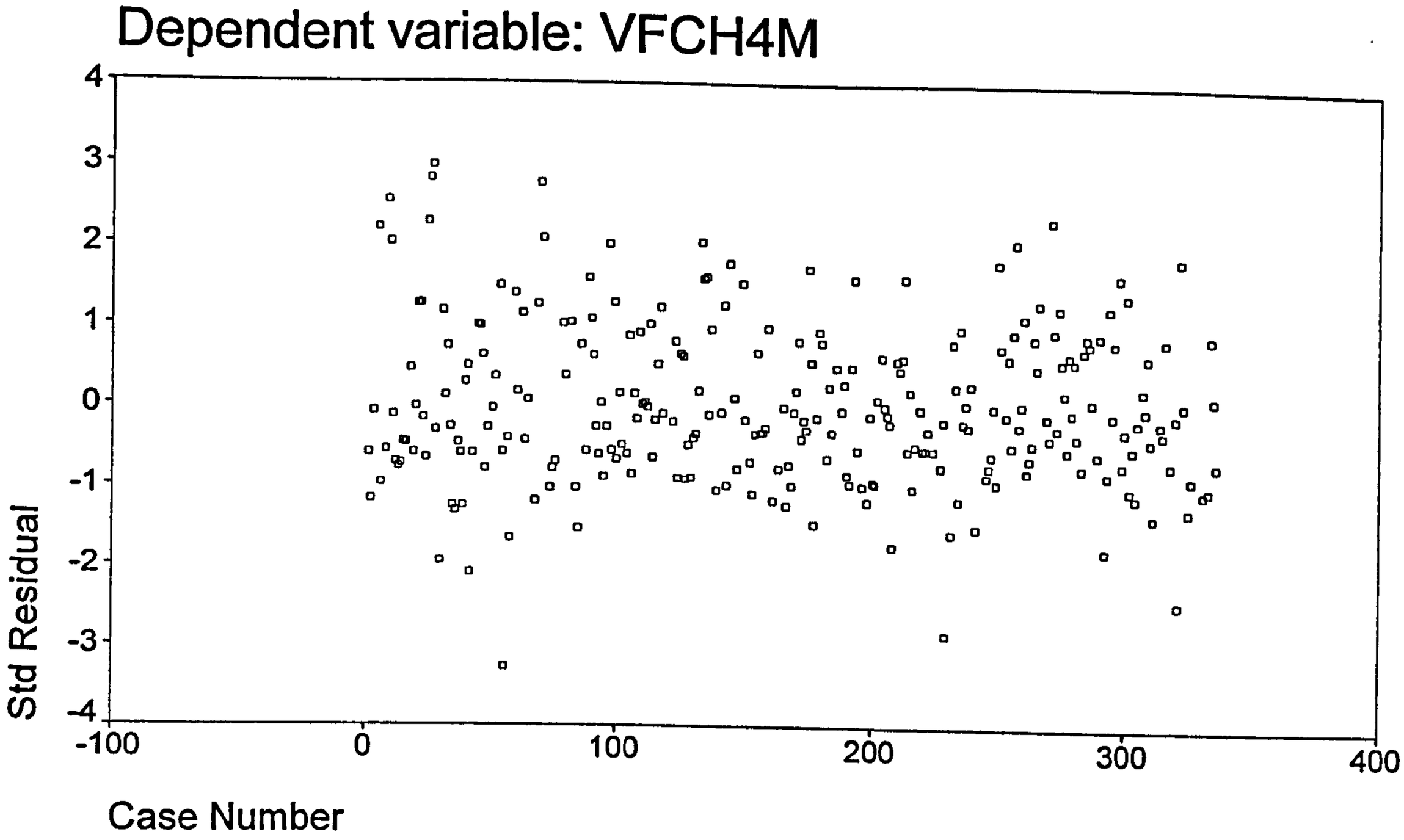
- -

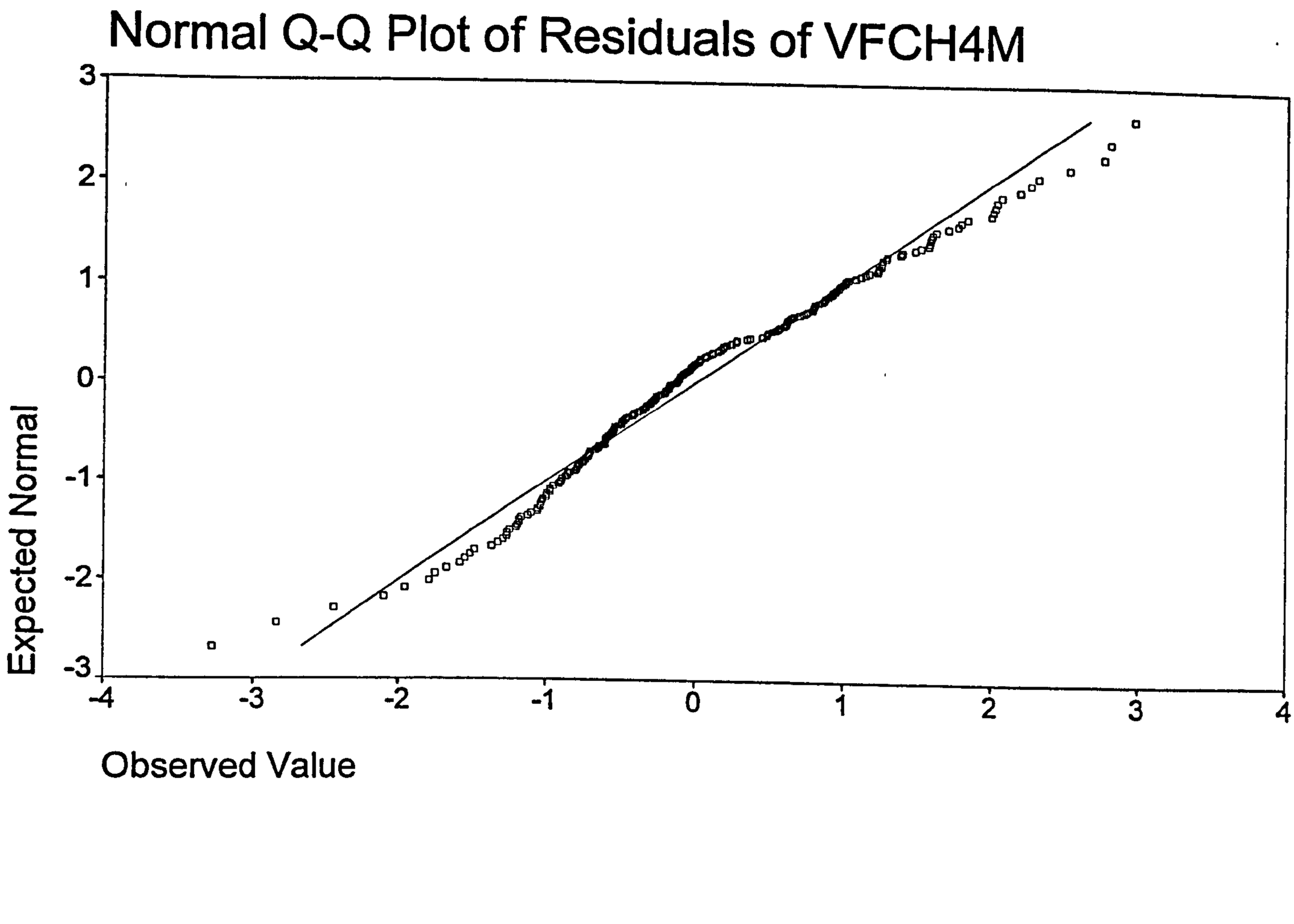
Hi-Res Chart # 41:Observed, predicted, residuals for vfch4m
Hi-Res Chart # 42:Case number vs. std. resid. for vfch4m
Hi-Res Chart # 43:Normal q-q plot of residuals of vfch4m
Hi-Res Chart # 44:Detrended normal q-q plot of residuals of vfch4m

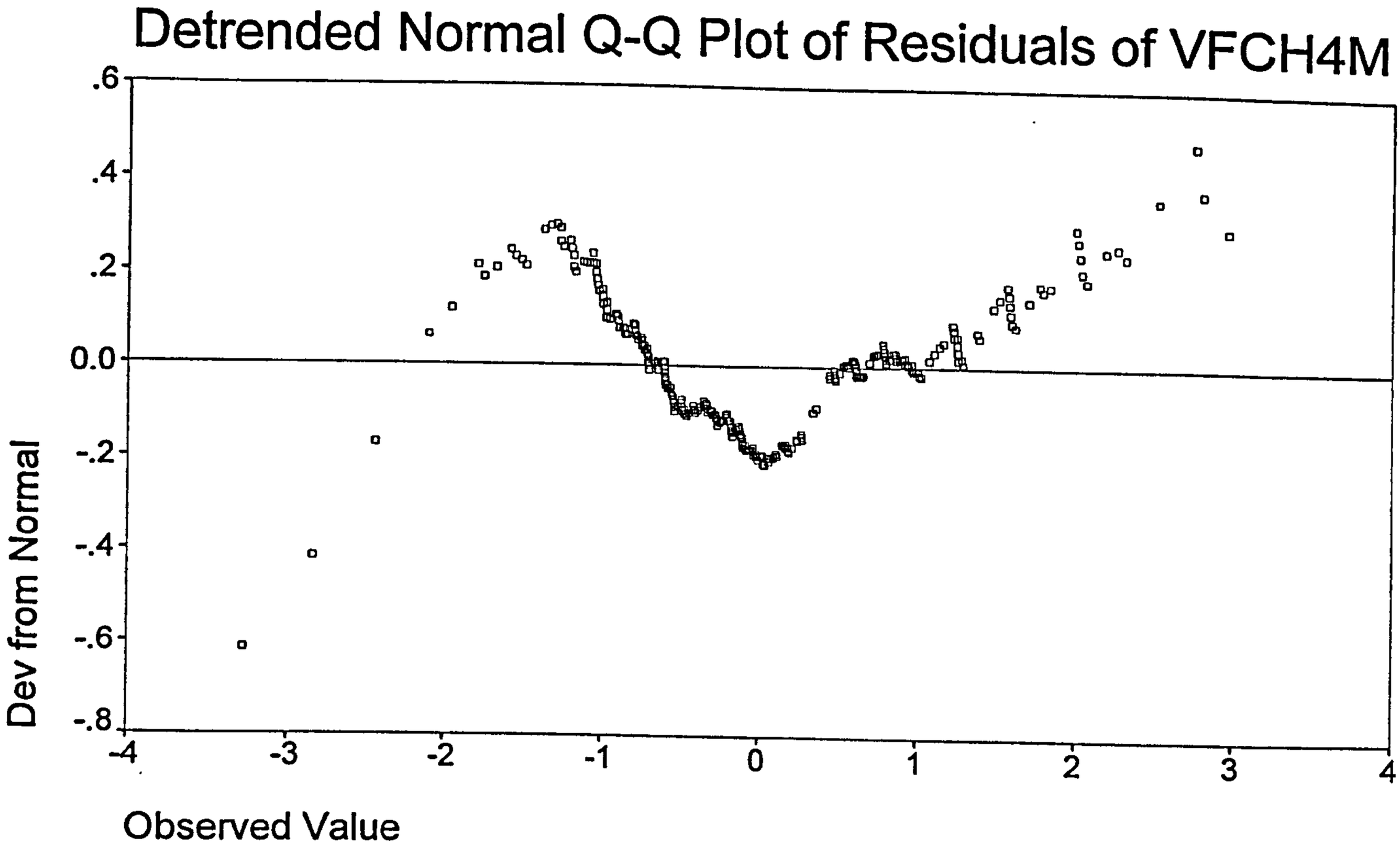
* * * * * \

Dependent variable: VFCH4M




Dependent variable: VFCH4M
Std Residual
4
3
2
1
0
-1
-2
-3
-4
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH4M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-4
-3
-2
-1
0
1
2
3
4


Detrended Normal Q-Q Plot of Residuals of VFCH4M
Dev from Normal
.6
.4
.2
0.0
-.2
-.4
-.6
-.8
-4
-3
-2
-1
0
1
2
3
4
Observed Value

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL 8.

CHANGE IN VF-14 SCORE AND CHANGE IN BETTER EYE VISUAL ACUITY 4 MONTHS

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

241 cases accepted.
0 cases rejected because of out-of-range factor values.
49 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH4M

Cochrans C(120,2) = .51594, P = .727 (approx.)
Bartlett-Box F(1,105222) = .10103, P = .751

- -

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Combined Observed Means for OH
Variable .. VFCH4M

OH		
0	WGT.	19.77907
	UNWGT.	19.77907
1	WGT.	20.96078
	UNWGT.	20.96078

- -

Variable .. AGE

OH		
0	WGT.	73.86471
	UNWGT.	73.86471
1	WGT.	77.12676
	UNWGT.	77.12676

- -

Variable .. BVCH4M

OH		
0	WGT.	1.17647
	UNWGT.	1.17647
1	WGT.	1.22535
	UNWGT.	1.22535

- -

* * * * * * Analysis of Variance -- design 1 * * * * * *

Tests of Significance for VFCH4M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	93904.30	237	396.22		
REGRESSION	14989.79	2	7494.89	18.92	.000
OH	241.42	1	241.42	.61	.436
(Model)	15059.72	3	5019.91	12.67	.000
(Total)	108964.03	240	454.02		

R-Squared = .138
Adjusted R-Squared = .127

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE	
VARIABLE	AGE	BVCH4M
VFCH4M	-.269	.915

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
AGE	.073
BVCH4M	.837

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.138
OH	.003

- -

Estimates for VFCH4M adjusted for 2 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	-1.1168132	1.43075	-.78058	.43583	-3.93543	1.70180

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH4M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
AGE	-.40001	-.15224	.162	-2.464	.014
BVCH4M	5.17459	.35789	.878	5.891	.000

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
AGE	-.720	-.080	.025
BVCH4M	3.444	6.905	.128

- -

Adjusted and Estimated Means
Variable .. VFCH4M

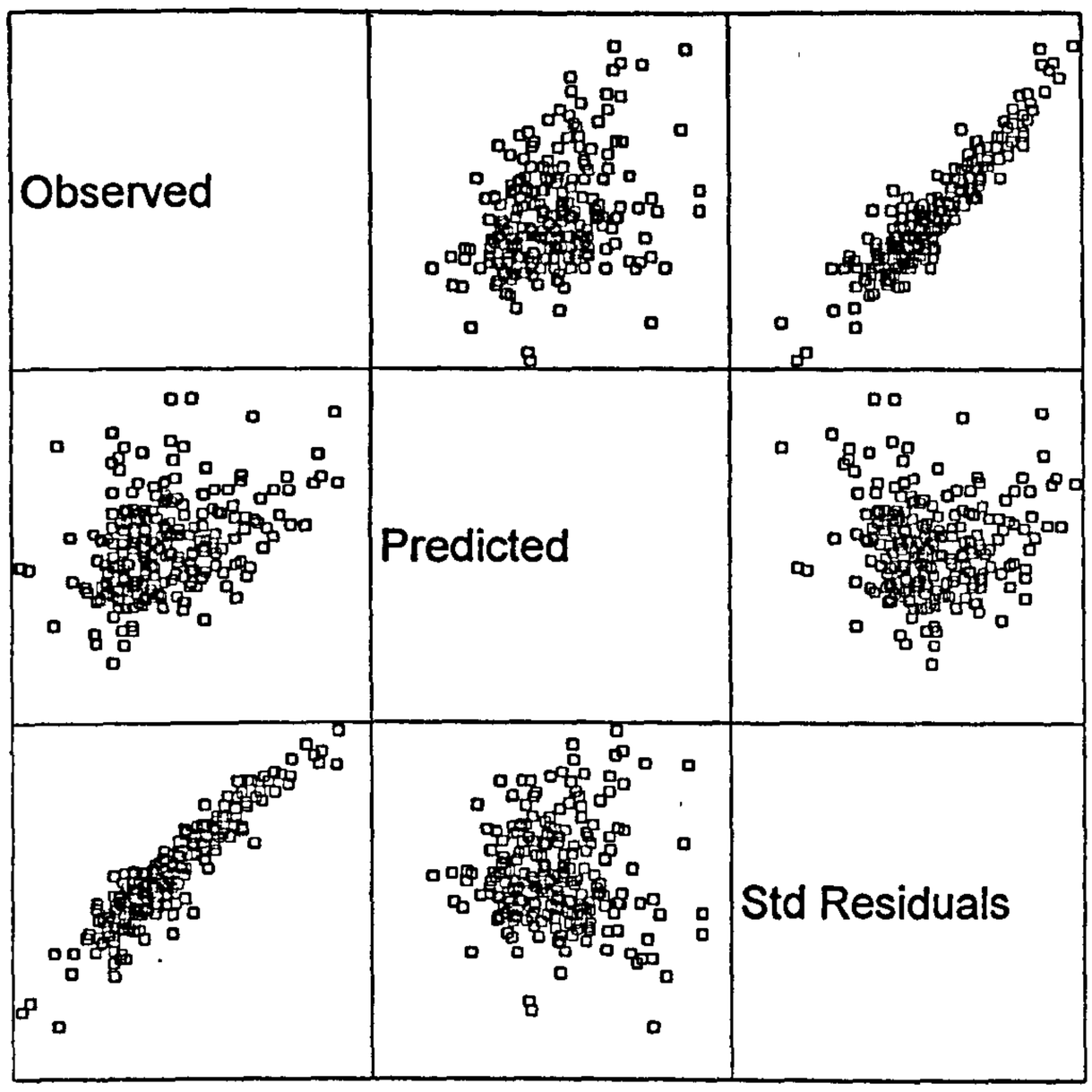
CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	19.779	19.253	19.779	.000	.000
2	20.961	21.487	20.961	.000	.000

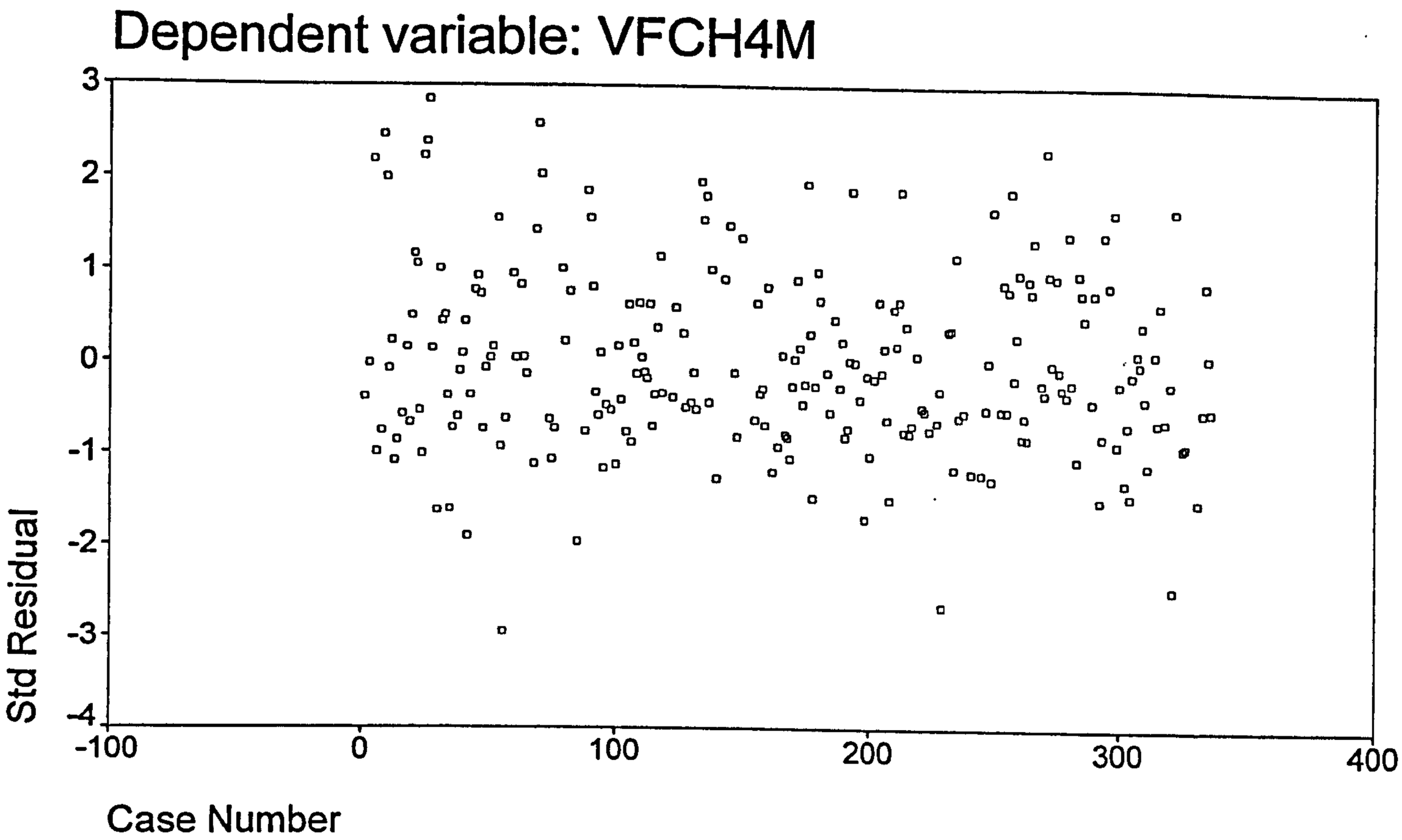
- -

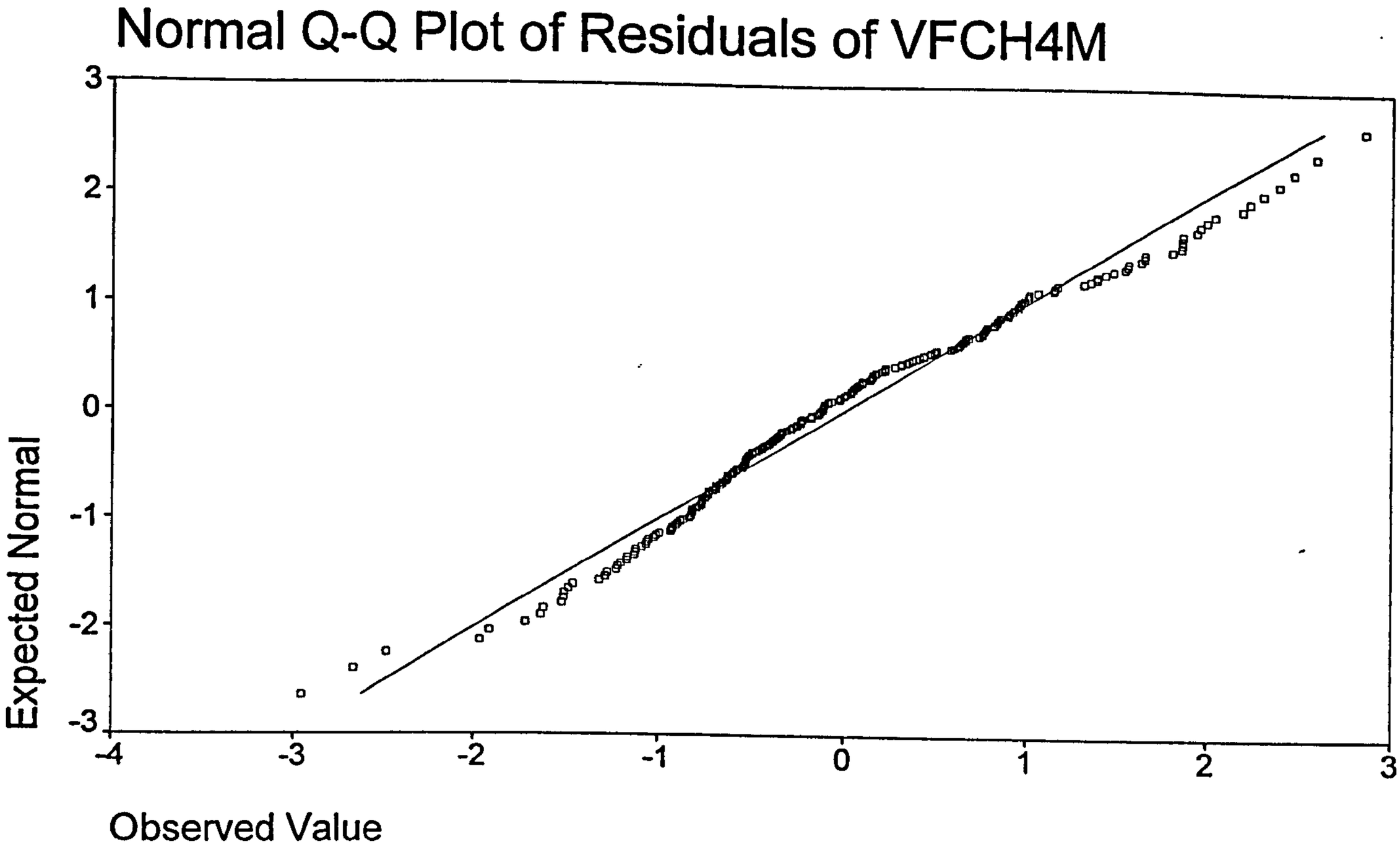
Hi-Res Chart # 45:Observed, predicted, residuals for vfch4m
Hi-Res Chart # 46:Case number vs. std. resid. for vfch4m
Hi-Res Chart # 47:Normal q-q plot of residuals of vfch4m
Hi-Res Chart # 48:Detrended normal q-q plot of residuals of vfch4m

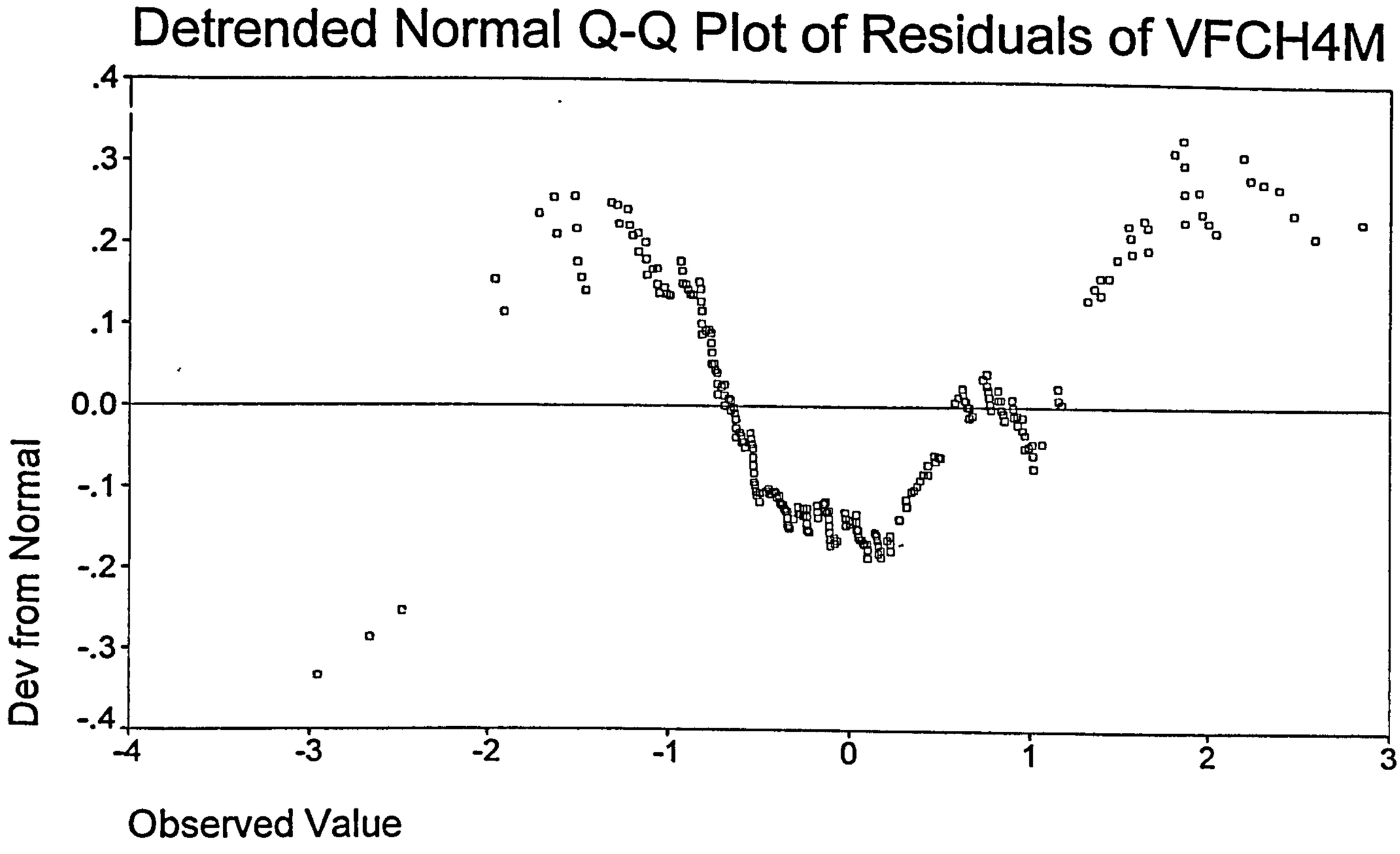
* * * * * \

Dependent variable: VFCH4M




Dependent variable: VFCH4M
Std Residual
3
2
1
0
-1
-2
-3
-4
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH4M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-4
-3
-2
-1
0
1
2
3


Detrended Normal Q-Q Plot of Residuals of VFCH4M
.4
.3
.2
.1
0.0
-.1
-.2
-.3
-.4
Dev from Normal
-4
-3
-2
-1
0
1
2
3
Observed Value

Appendix D2

Analysis of Covariance Models :

Determinants of Change in Visual Function at 12 Months

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL A

CHANGE IN VF-14 SCORE AT 12 MONTHS AND PRE-OP BETTER EYE VISUAL ACUITY [redacted]

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

261 cases accepted.
0 cases rejected because of out-of-range factor values.
17 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests
Variable .. VFCH12M

Cochrans C(64,4) = .30660, P = .296 (approx.)
Bartlett-Box F(3,40807) = 1.67464, P = .170

- -

Combined Observed Means for OH
Variable .. VFCH12M

OH		
0	WGT.	24.17131
	UNWGT.	26.08296
1	WGT.	20.07914
	UNWGT.	23.07568

- -

Variable .. BVHI

OH		
0	WGT.	9.90556
	UNWGT.	9.86465
1	WGT.	9.29630
	UNWGT.	9.14430

- -

Variable .. AGE

OH		
0	WGT.	74.07222
	UNWGT.	74.21043
1	WGT.	77.07407
	UNWGT.	76.93888

- -

Combined Observed Means for E212M
Variable .. VFCH12M

E212M		
0	WGT.	19.36727
	UNWGT.	19.03084
1	WGT.	31.19276
	UNWGT.	30.12780

- -

Variable .. BVHI

E212M		
0	WGT.	9.78689
	UNWGT.	9.69892
1	WGT.	9.55128
	UNWGT.	9.31003

- -

Variable .. AGE

E212M		
0	WGT.	74.96721
	UNWGT.	75.47669
1	WGT.	75.08974
	UNWGT.	75.67261

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Tests of Significance for VFCH12M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	92049.55	255	360.98		
REGRESSION	14564.17	2	7282.08	20.17	.000
OH	942.92	1	942.92	2.61	.107
E212M	3530.84	1	3530.84	9.78	.002
OH BY E212M	120.11	1	120.11	.33	.565
(Model)	22610.22	5	4522.04	12.53	.000
(Total)	114659.77	260	441.00		

R-Squared = .197
Adjusted R-Squared = .181

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE	
VARIABLE	BVHI	AGE
VFCH12M	-.683	-.265

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
BVHI	.466
AGE	.070

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.137
OH	.010
E212M	.037
OH BY E212M	.001

- -

Estimates for VFCH12M adjusted for 2 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	2.46774859	1.52687	1.61621	.10729	-.53914	5.47464

E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
3	-4.7020384	1.50345	-3.12750	.00197	-7.66279	-1.74128

OH BY E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
4	-.86437205	1.49851	-.57682	.56457	-3.81540	2.08665

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH12M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
BVHI	-4.61024	-.35530	.764	-6.033	.000
AGE	-.51046	-.19620	.153	-3.345	.001

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
BVHI	-6.115	-3.105	.125
AGE	-.811	-.210	.042

- -

Adjusted and Estimated Means
Variable .. VFCH12M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	20.150	21.481	20.150	.000	.000
2	32.016	32.613	32.016	.000	.000
3	17.911	18.274	17.911	.000	.000
4	28.240	25.949	28.240	.000	.000

Hi-Res Chart # 69:Observed, predicted, residuals for vfch12m
Hi-Res Chart # 70:Case number vs. std. resid. for vfch12m
Hi-Res Chart # 71:Normal q-q plot of residuals of vfch12m
Hi-Res Chart # 72:Detrended normal q-q plot of residuals of vfch12m
****

Combined Adjusted Means for OH
Variable .. VFCH12M

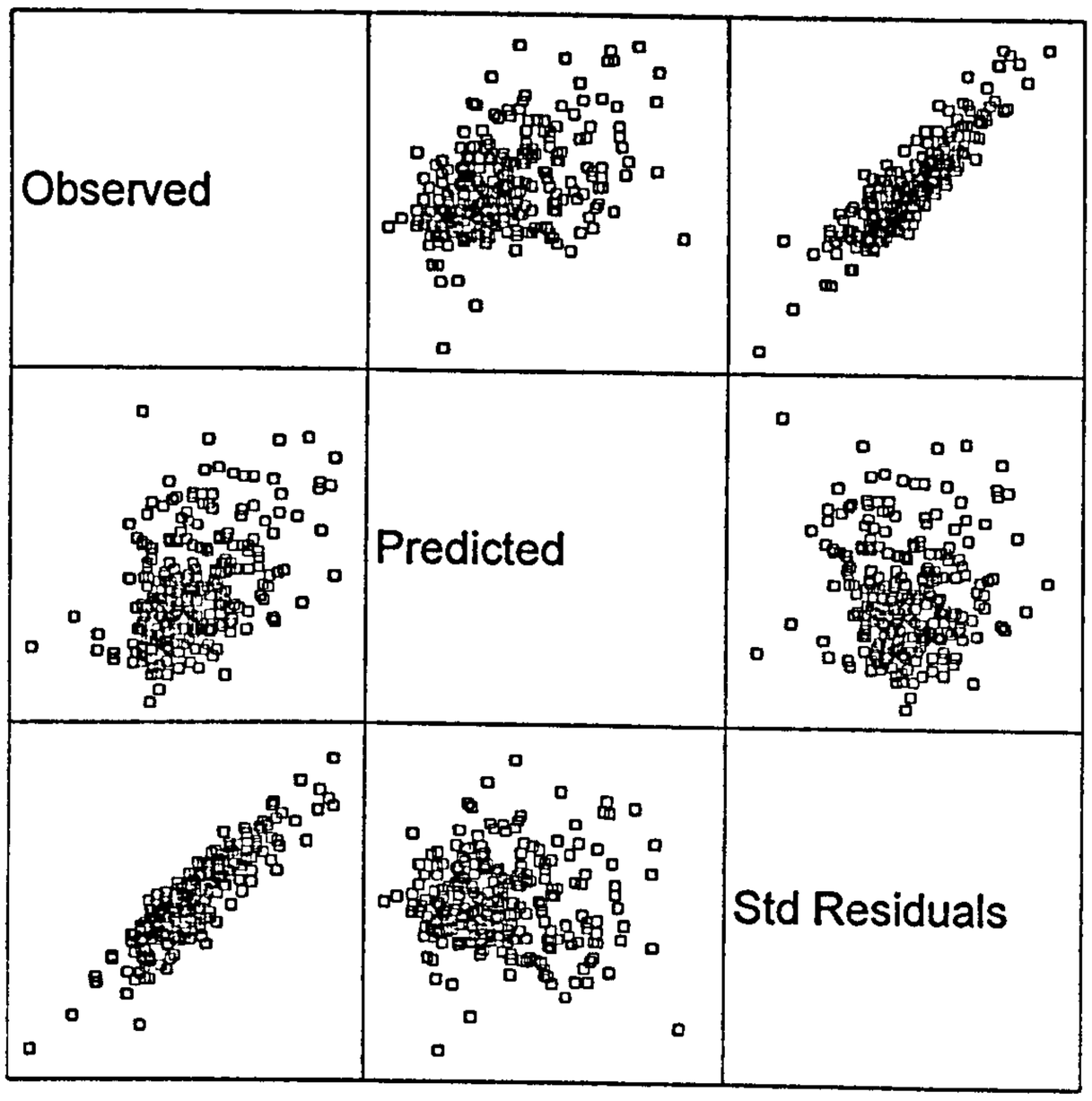
OH		
0	UNWGT.	27.04707
1	UNWGT.	22.11157

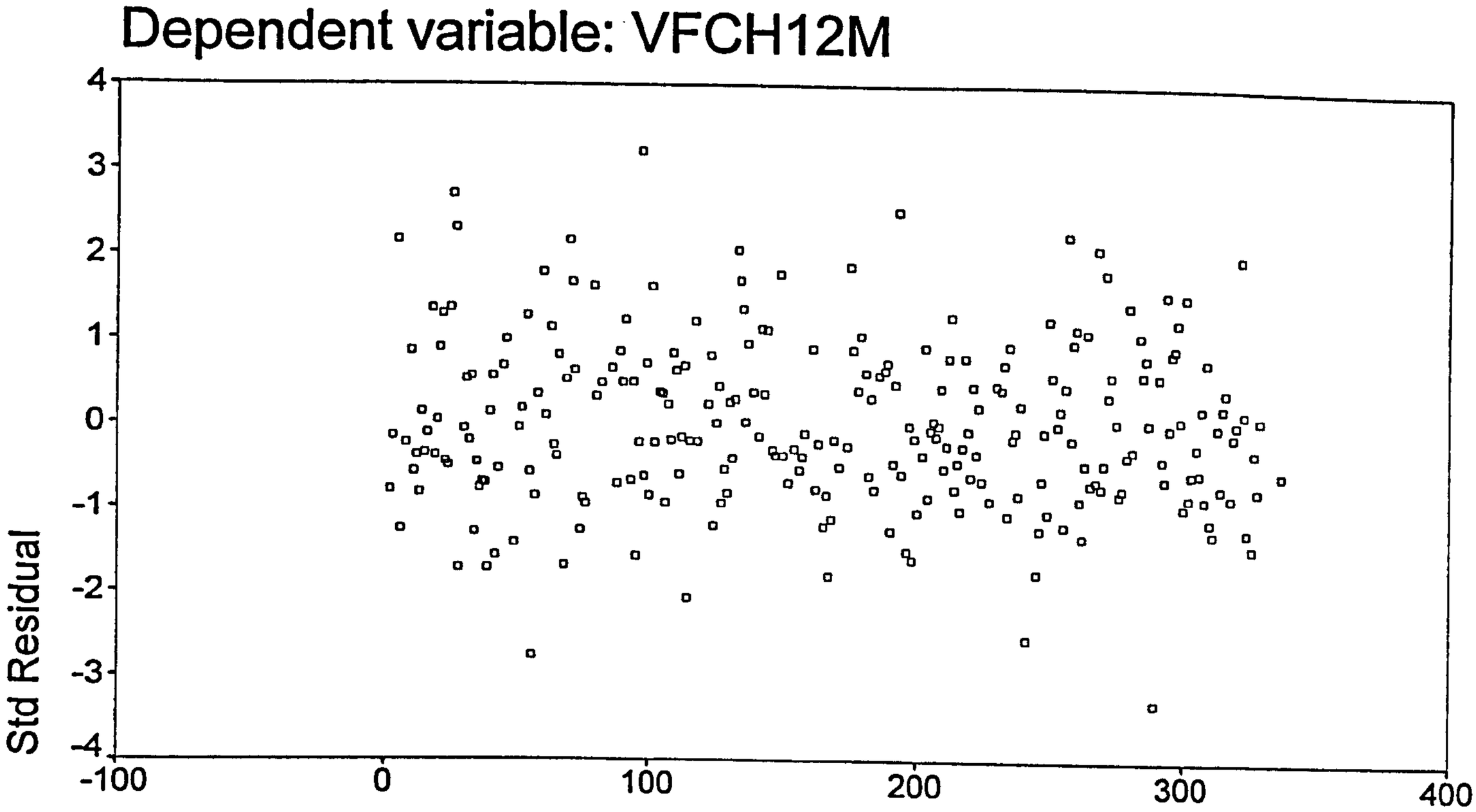
- -

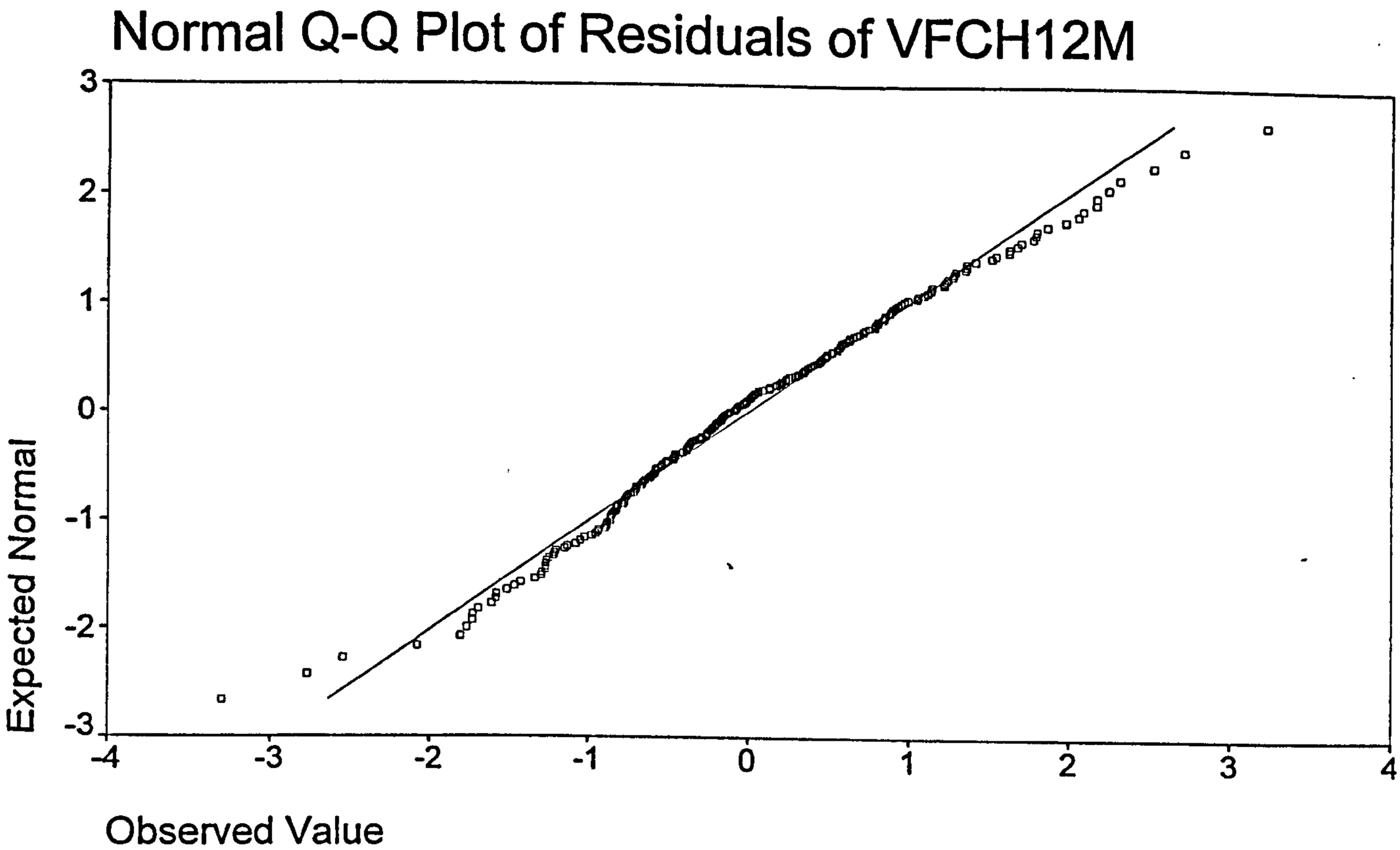
Combined Adjusted Means for E212M
Variable .. VFCH12M

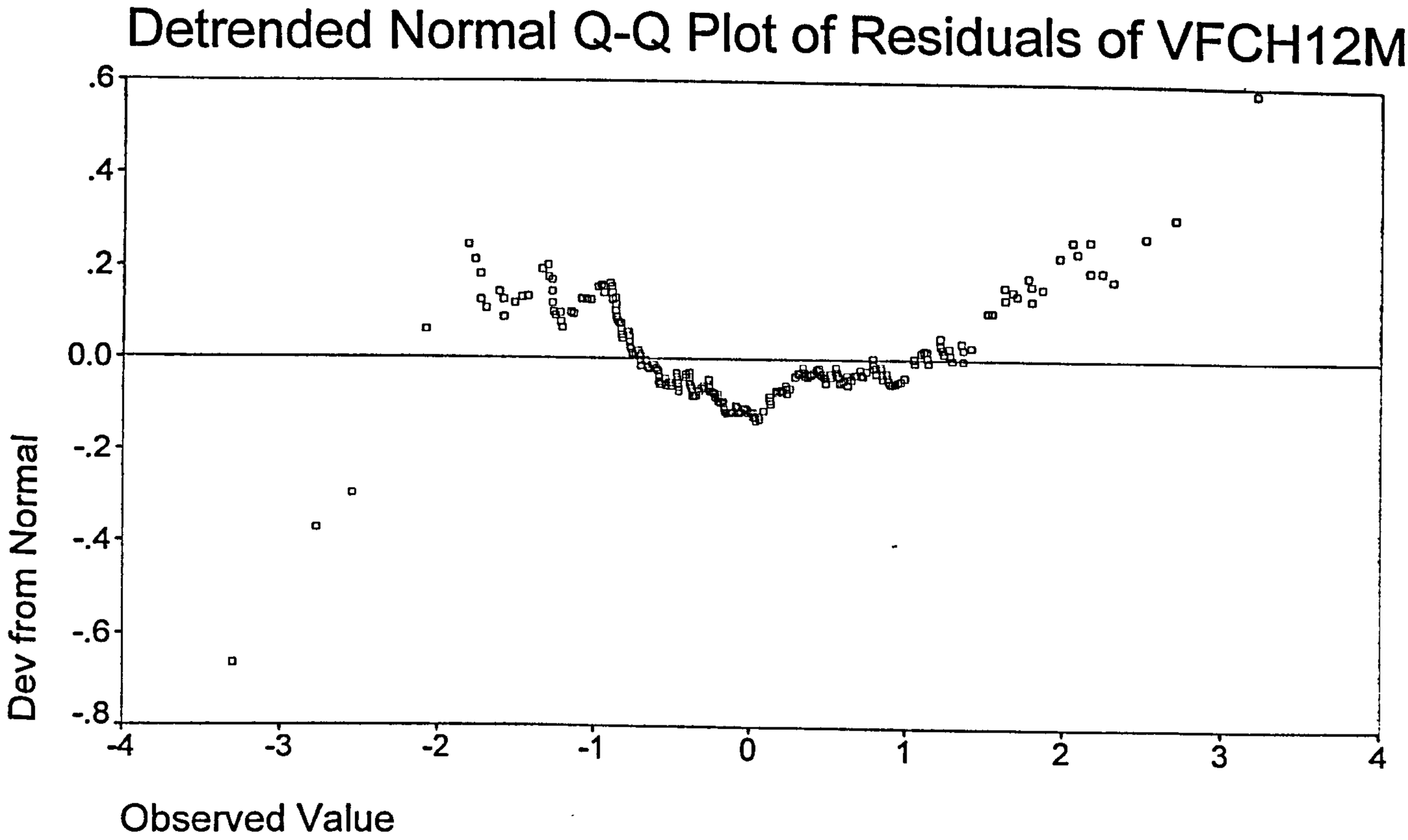
E212M		
0	UNWGT.	19.87728
1	UNWGT.	29.28136

Dependent variable: VFCH12M




Dependent variable: VFCH12M
Std Residual
4
3
2
1
0
-1
-2
-3
-4
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH12M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-4
-3
-2
-1
0
1
2
3
4


Detrended Normal Q-Q Plot of Residuals of VFCH12M
.6
.4
.2
0.0
-.2
-.4
-.6
-.8
Dev from Normal
-4
-3
-2
-1
0
1
2
3
4
Observed Value

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL g.

CHANGE IN VF-14 SCORE AT 12 MONTHS AND CHANGE IN BETTER EYE VISUAL ACUITY AT 12 MONTHS

* * * * * * Analysis of Variance * * * * * *

210 cases accepted.
0 cases rejected because of out-of-range factor values.
68 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH12M

Cochrans C(52,4) = .31780, P = .242 (approx.)
Bartlett-Box F(3,26456) = 2.24987, P = .081

- -

Combined Observed Means for OH
Variable .. VFCH12M

OH		
0	WGT.	24.52758
	UNWGT.	26.36946
1	WGT.	18.56333
	UNWGT.	21.37541

- -

Variable .. BVCH12M

OH		
0	WGT.	1.26027
	UNWGT.	1.34736
1	WGT.	1.20313
	UNWGT.	1.33571

- -

Variable .. AGE

OH		
0	WGT.	74.01370
	UNWGT.	74.26783
1	WGT.	76.73438
	UNWGT.	77.08714

- -

Combined Observed Means for E212M
Variable .. VFCH12M

E212M		
0	WGT.	19.27357
	UNWGT.	18.57162
1	WGT.	30.72802
	UNWGT.	29.17326

- -

Variable .. BVCH12M

E212M		
0	WGT.	1.08844
	UNWGT.	1.09124
1	WGT.	1.60317
	UNWGT.	1.59184

- -

Variable .. AGE

E212M		
0	WGT.	74.50340
	UNWGT.	74.97742
1	WGT.	75.63492
	UNWGT.	76.37755

* * * * * * Analysis of Variance -- design 1 * * * * * *

Tests of Significance for VFCH12M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	66448.20	204	325.73		
REGRESSION	22774.84	2	11387.42	34.96	.000
OH	440.61	1	440.61	1.35	.246
E212M	1943.82	1	1943.82	5.97	.015
OH BY E212M	7.13	1	7.13	.02	.882
(Model)	29538.21	5	5907.64	18.14	.000
(Total)	95986.41	209	459.27		

R-Squared = .308
Adjusted R-Squared = .291

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE	
VARIABLE	BVCH12M	AGE
VFCH12M	.889	-.242

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
BVCH12M	.791
AGE	.058

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.255
OH	.007
E212M	.028
OH BY E212M	.000

- -

Estimates for VFCH12M adjusted for 2 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	1.85205413	1.59240	1.16306	.24617	-1.28763	4.99174

E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
3	-3.8944594	1.59421	-2.44287	.01542	-7.03770	-.75121

OH BY E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
4	-.23339845	1.57699	-.14800	.88249	-3.34269	2.87590

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH12M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
BVCH12M	6.81961	.47446	.849	8.031	.000
AGE	-.42937	-.16206	.157	-2.735	.007

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
BVCH12M	5.145	8.494	.240
AGE	-.739	-.120	.035

- -

Adjusted and Estimated Means
Variable .. VFCH12M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	20.767	21.597	20.767	.000	.000
2	31.972	29.852	31.972	.000	.000
3	16.376	18.359	16.376	.000	.000
4	26.375	25.681	26.375	.000	.000

Hi-Res Chart # 73:Observed, predicted, residuals for vfch12m
Hi-Res Chart # 74:Case number vs. std. resid. for vfch12m
Hi-Res Chart # 75:Normal q-q plot of residuals of vfch12m
Hi-Res Chart # 76:Detrended normal q-q plot of residuals of vfch12m
****

Combined Adjusted Means for OH
Variable .. VFCH12M

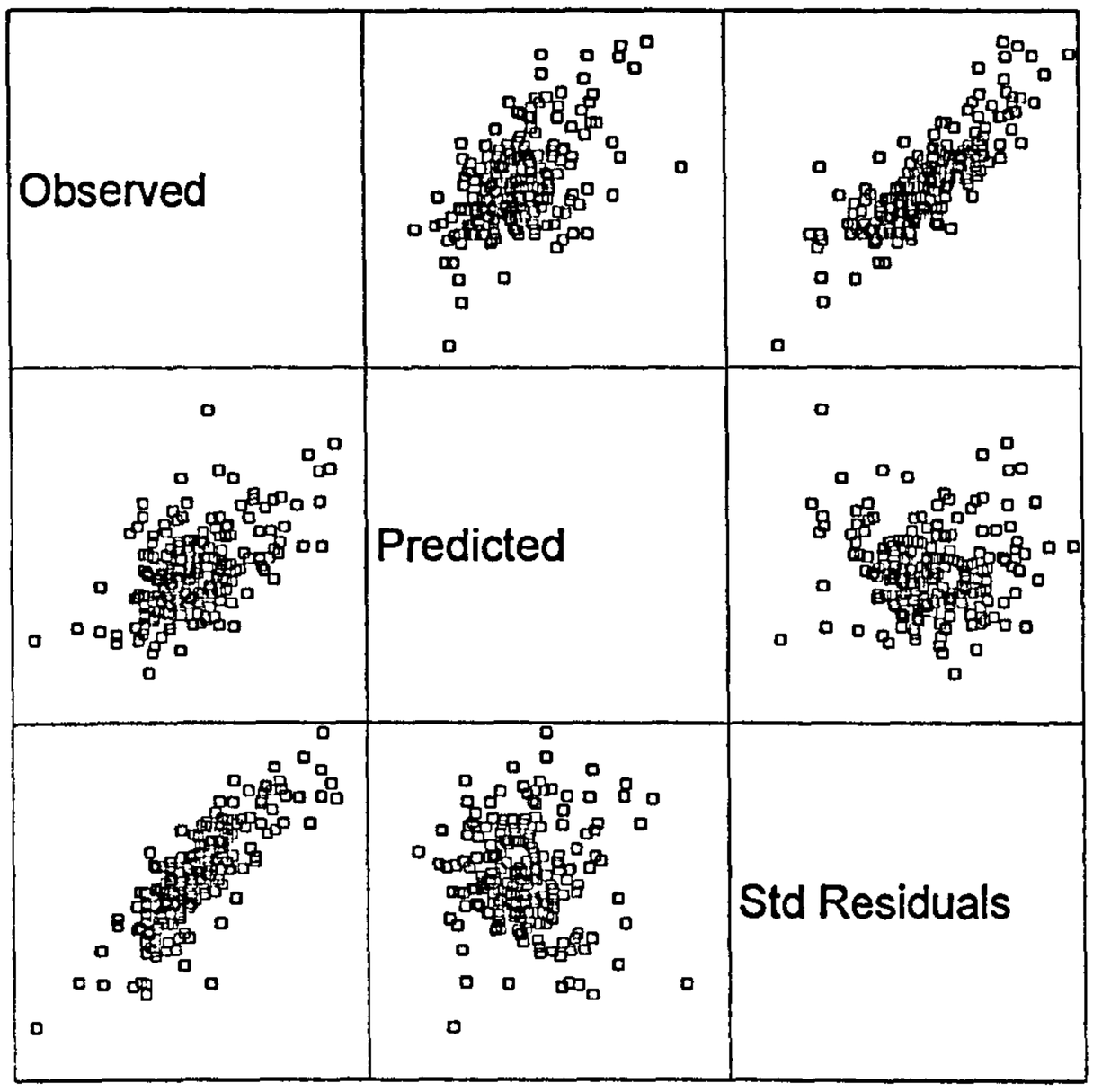
OH		
0	UNWGT.	25.72449
1	UNWGT.	22.02038

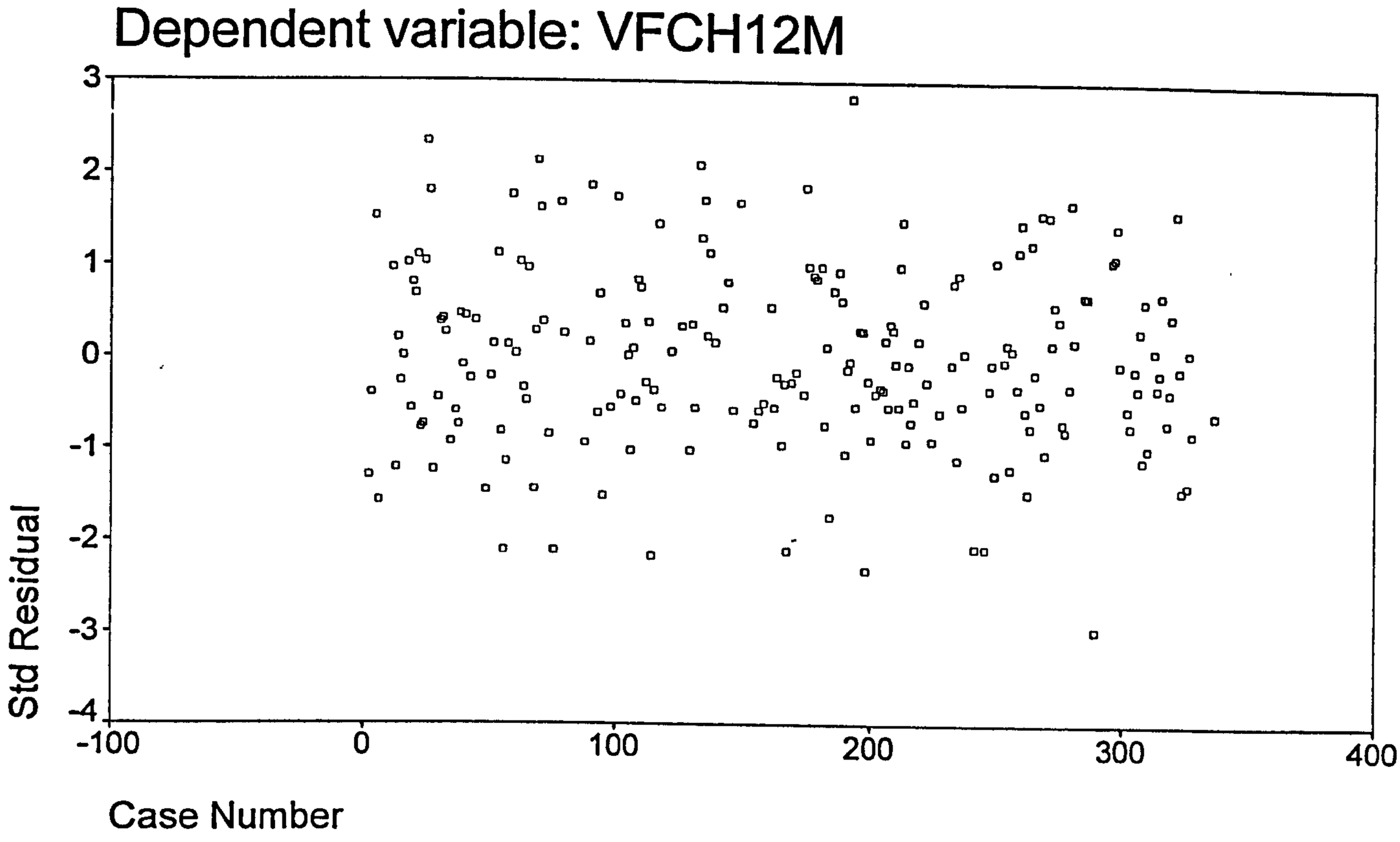
- -

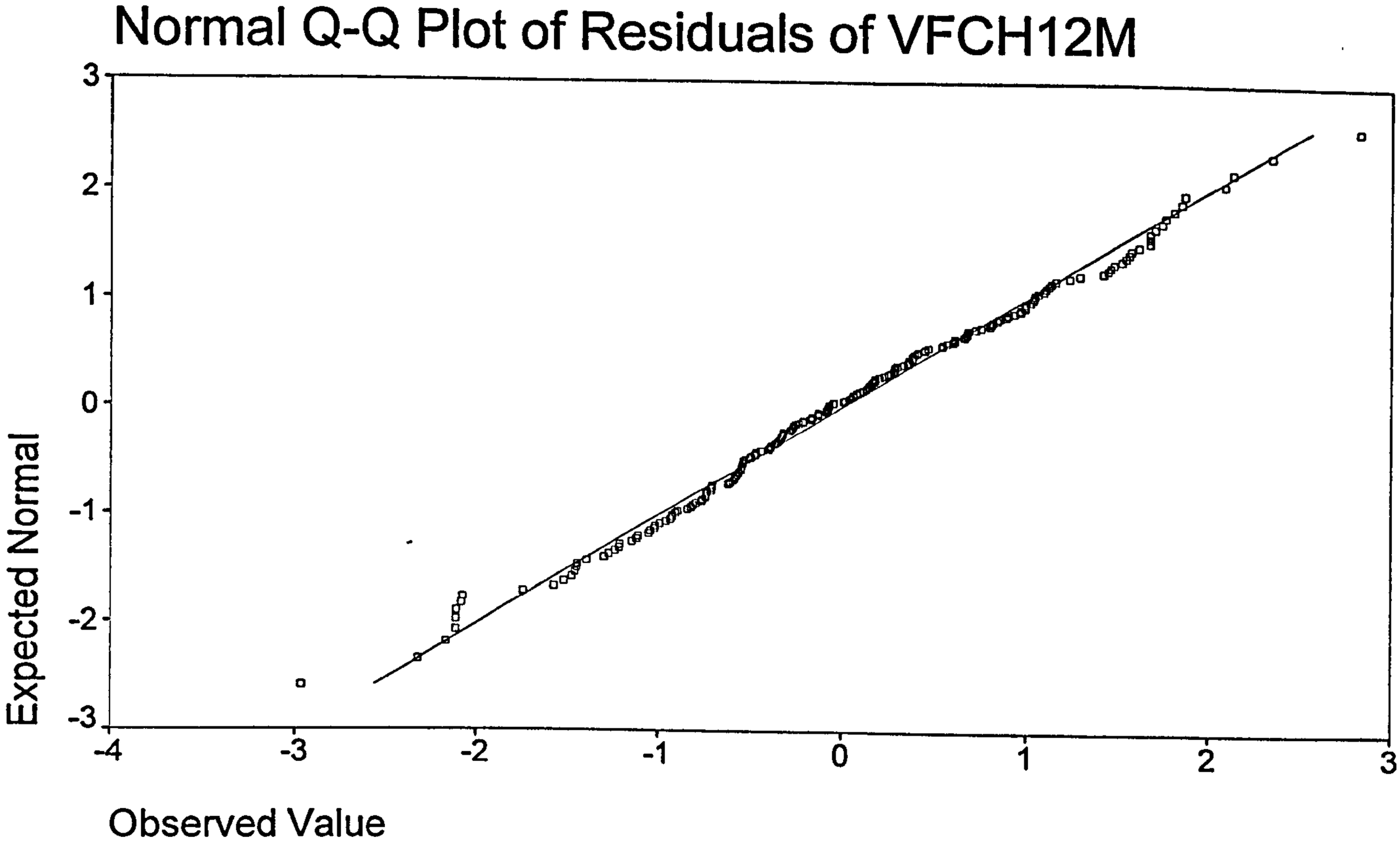
Combined Adjusted Means for E212M
Variable .. VFCH12M

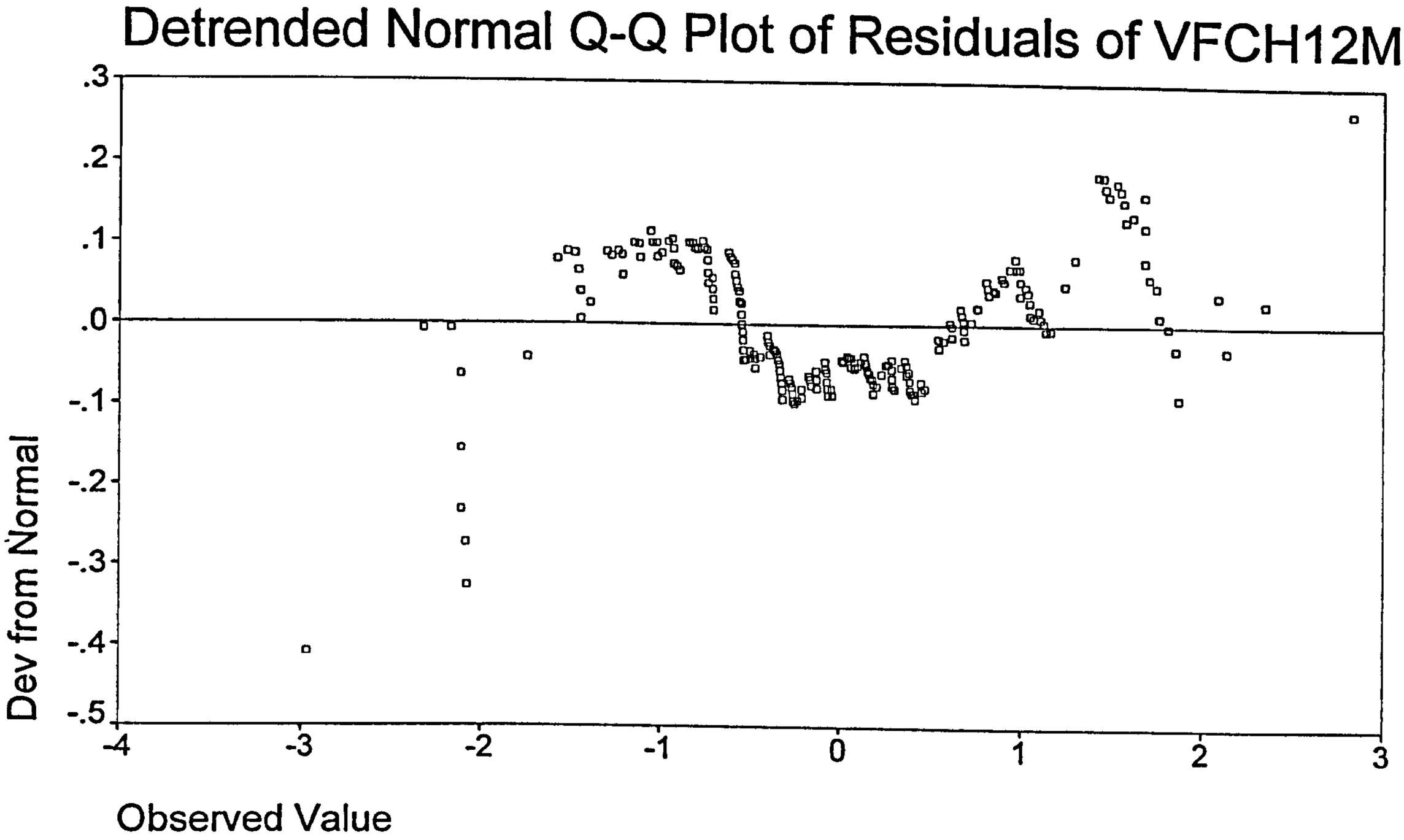
E212M		
0	UNWGT.	19.97798
1	UNWGT.	27.76690

Dependent variable: VFCH12M




Dependent variable: VFCH12M
Std Residual
3
2
1
0
-1
-2
-3
-4
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH12M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-4
-3
-2
-1
0
1
2
3


Detrended Normal Q-Q Plot of Residuals of VFCH12M
Dev from Normal
.3
.2
.1
.0
-.1
-.2
-.3
-.4
-.5
-4
-3
-2
-1
0
1
2
3
Observed Value

Appendix D3

Analysis of Covariance Models :

Determinants of Change in Visual Function at 4 Months

Adjusting for pre-operative factors (capacity for change)

- model 1
- model 2

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL 1a.

CHANGE IN VF-14 SCORE AT 4 MONTHS AND PRE-OP BETTER EYE VISUAL ACUITY,
ADJUSTING FOR PRE-OP VF-14 SCORE.

* * * * * * Analysis of Variance * * * * * *

272 cases accepted.
0 cases rejected because of out-of-range factor values.
18 cases rejected because of missing data.
2 non-empty cells.
1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH4M

Cochrans C(135,2) = .51300, P = .763 (approx.)
Bartlett-Box F(1,146464) = .07847, P = .779

- -

Combined Observed Means for OH
Variable .. VFCH4M

OH		
0	WGT.	19.53753
	UNWGT.	19.53753
1	WGT.	20.51897
	UNWGT.	20.51897

- -

Variable .. AGE

OH		
0	WGT.	73.75401
	UNWGT.	73.75401
1	WGT.	76.69412
	UNWGT.	76.69412

- -

Variable .. BVHI

OH		
0	WGT.	9.87701
	UNWGT.	9.87701
1	WGT.	9.17647
	UNWGT.	9.17647

- -

Variable .. VFSD

OH		
0	WGT.	70.67745
	UNWGT.	70.67745
1	WGT.	65.52645
	UNWGT.	65.52645

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Tests of Significance for VFCH4M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	55800.84	267	208.99		
REGRESSION	65234.45	3	21744.82	104.05	.000
OH	81.61	1	81.61	.39	.533
(Model)	65290.74	4	16322.68	78.10	.000
(Total)	121091.58	271	446.83		

R-Squared = .539
Adjusted R-Squared = .532

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE		
VARIABLE	AGE	BVHI	VFSD
VFCH4M	-.097	-.374	-.978

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
AGE	.010
BVHI	.140
VFSD	.956

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.539
OH	.001

- -

Estimates for VFCH4M adjusted for 3 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	.606740626	.97094	.62490	.53257	-1.30493	2.51841

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH4M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
AGE	-.08873	-.03462	.115	-.774	.440
BVHI	2.02446	.15731	.692	2.925	.004
VFSD	-.75209	-.80859	.047	-15.905	.000

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
AGE	-.314	.137	.002
BVHI	.662	3.387	.031
VFSD	-.845	-.659	.487

- -

Adjusted and Estimated Means
Variable .. VFCH4M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	19.538	20.635	19.538	.000	.000
2	20.519	19.422	20.519	.000	.000

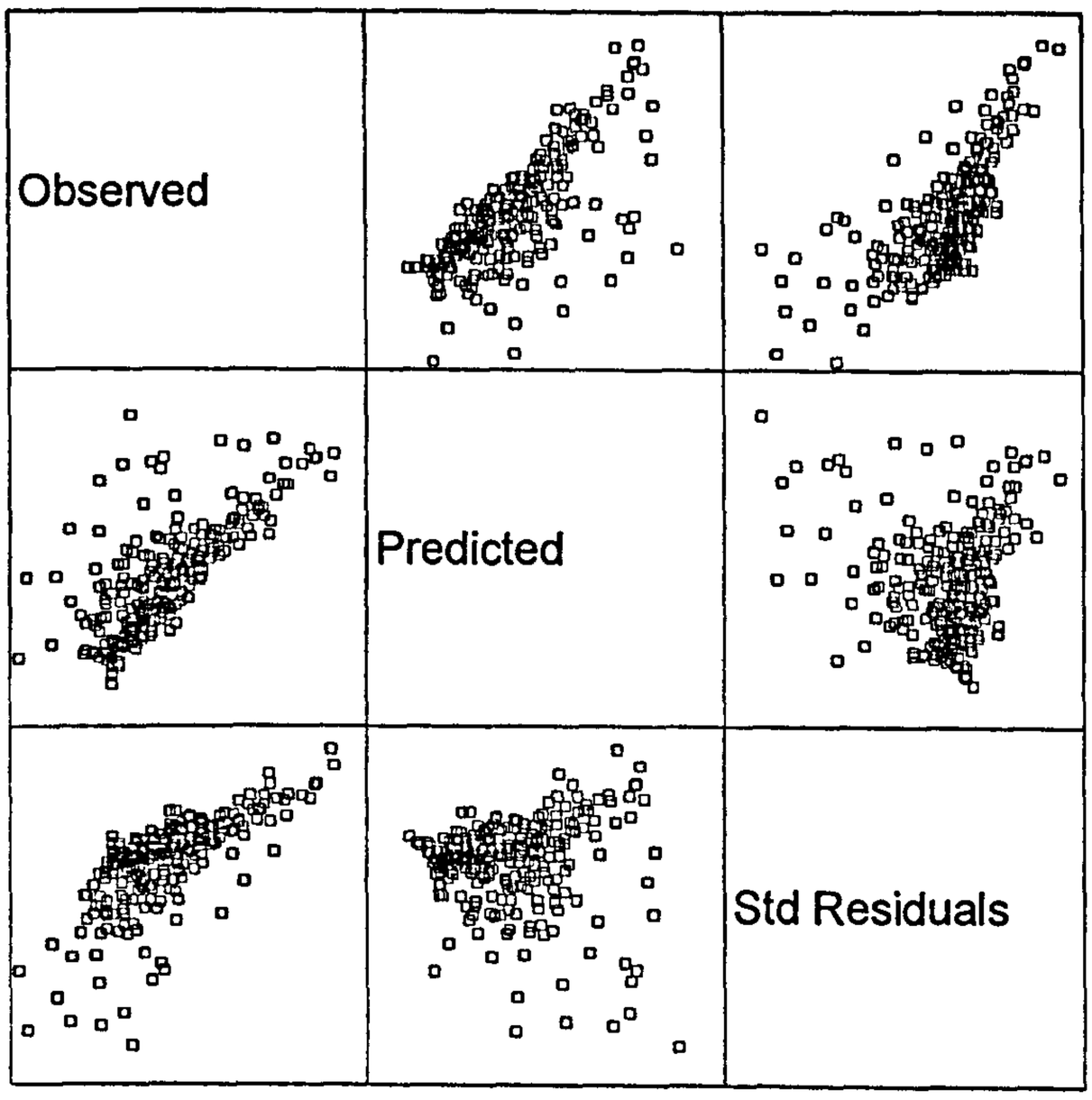
- -

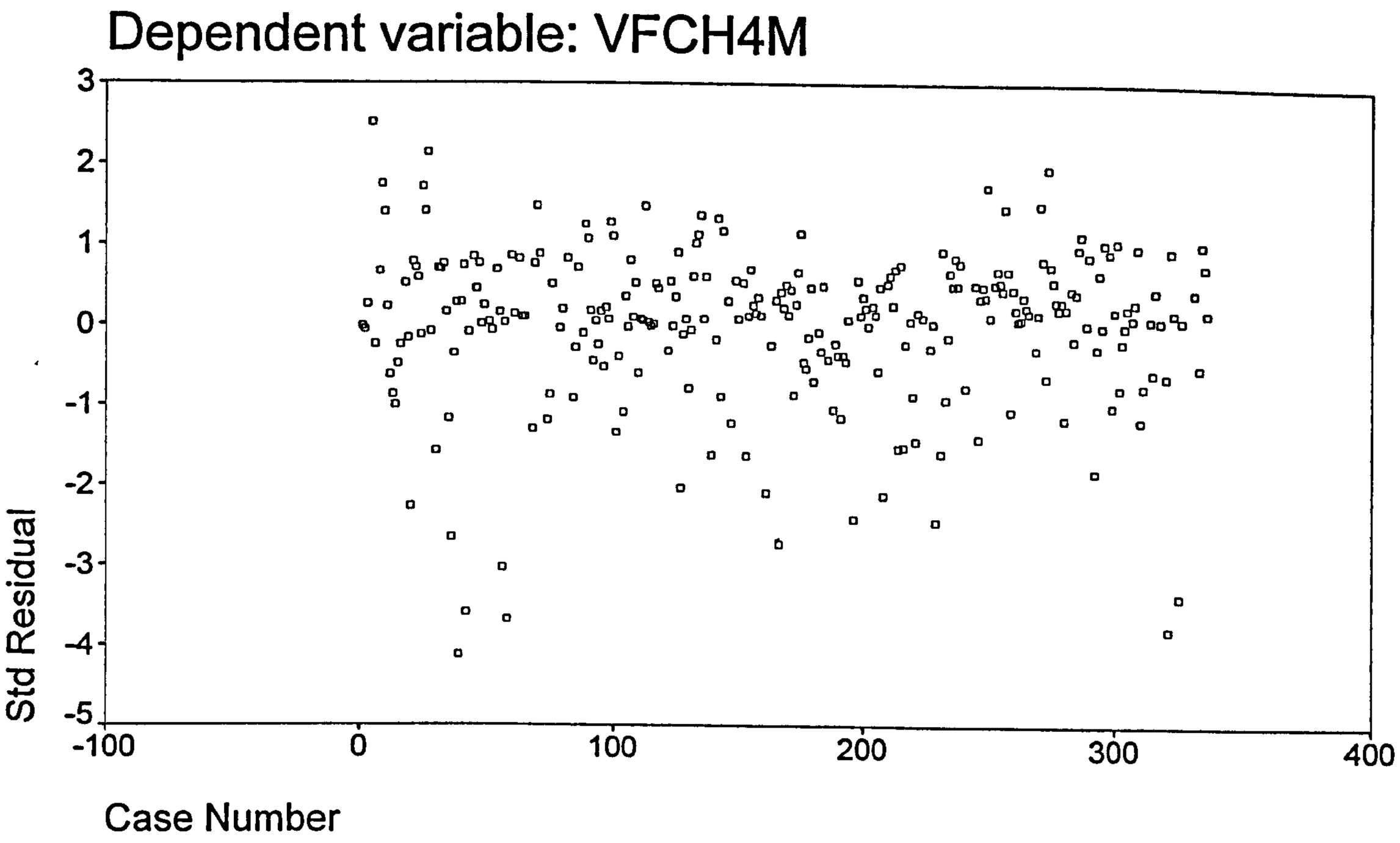
Hi-Res Chart # 49:Observed, predicted, residuals for vfch4m
Hi-Res Chart # 50:Case number vs. std. resid. for vfch4m
Hi-Res Chart # 51:Normal q-q plot of residuals of vfch4m
Hi-Res Chart # 52:Detrended normal q-q plot of residuals of vfch4m
****

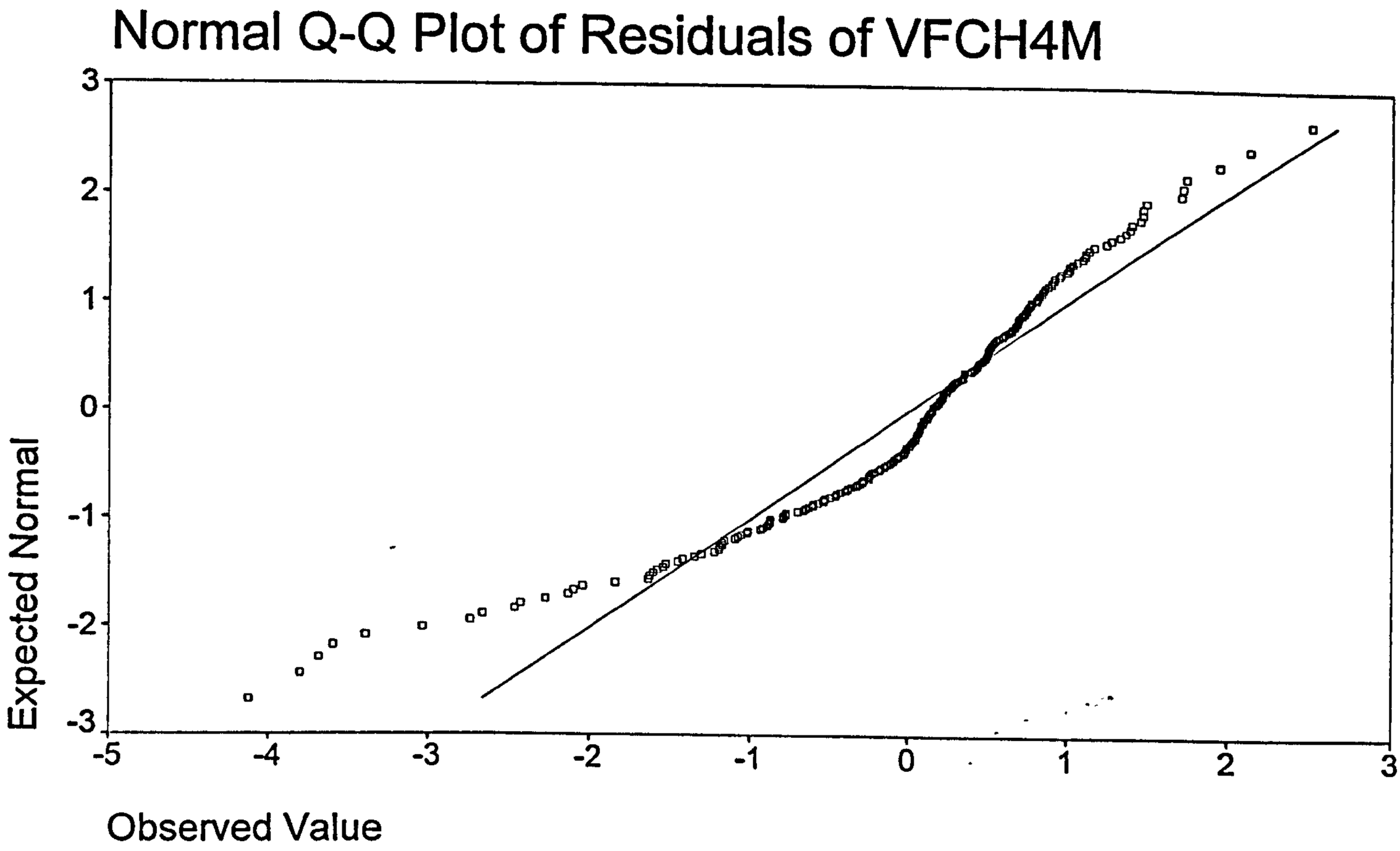
Combined Adjusted Means for OH
Variable .. VFCH4M

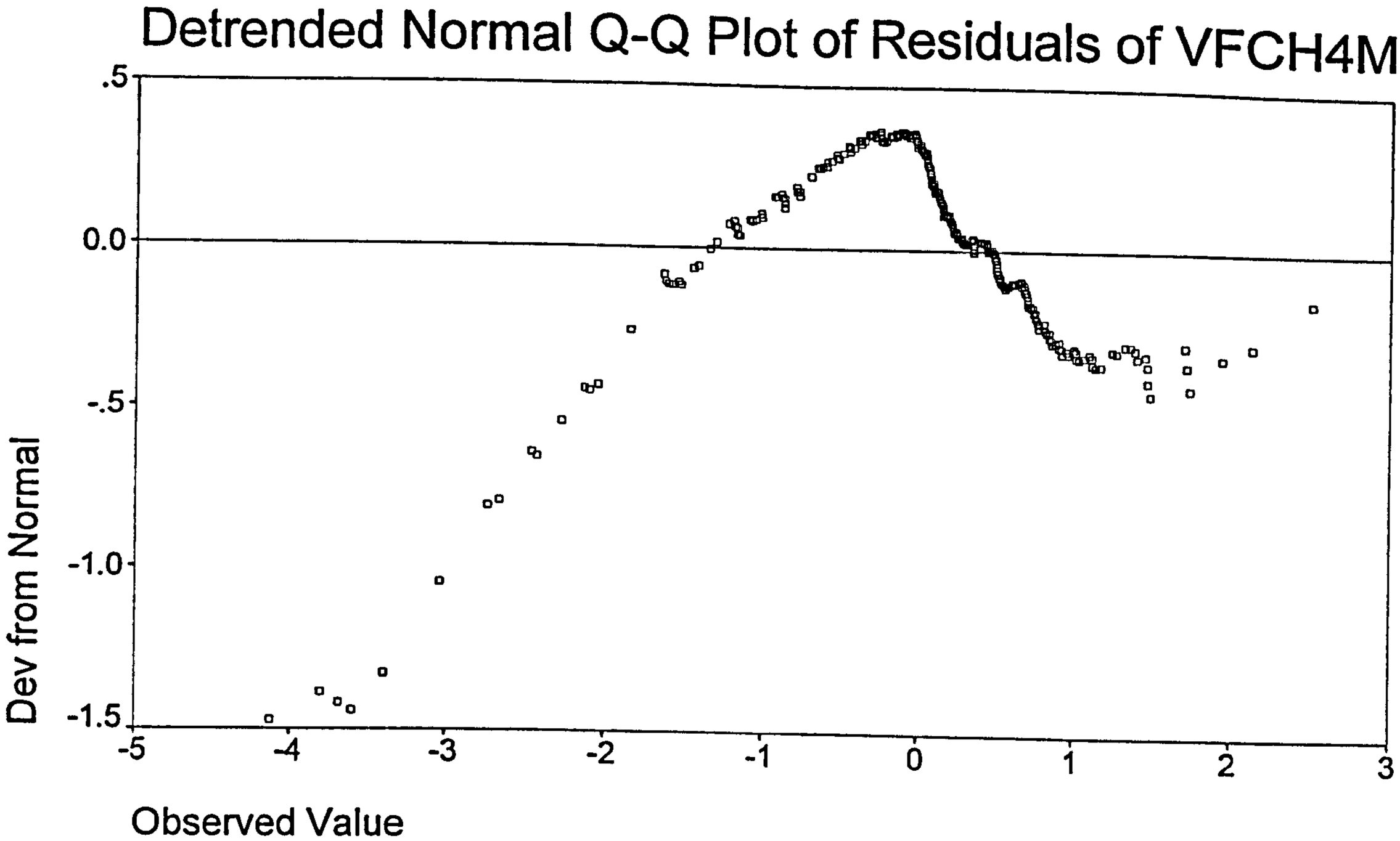
OH		
0	UNWGT.	20.63499
1	UNWGT.	19.42151

Dependent variable: VFCH4M




Dependent variable: VFCH4M
Std Residual
3
2
1
0
-1
-2
-3
-4
-5
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH4M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-5
-4
-3
-2
-1
0
1
2
3


Detrended Normal Q-Q Plot of Residuals of VFCH4M
.5
0.0
-.5
-1.0
-1.5
Dev from Normal
-5
-4
-3
-2
-1
0
1
2
3
Observed Value

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL 2■.

CHANGE IN VF-14 SCORE AT 4 MONTHS AND CHANGE IN BETTER EYE VISUAL ACUITY AT 4 MONTHS ADJUSTING FOR PRE-OP VF-14 SCORE AND PRE-OP BETTER EYE ACUITY.

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

241 cases accepted.
0 cases rejected because of out-of-range factor values.
49 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH4M

Cochrans C(120,2) = .51594, P = .727 (approx.)
Bartlett-Box F(1,105222) = .10103, P = .751

- -

Combined Observed Means for OH
Variable .. VFCH4M

OH		
0	WGT.	19.77907
	UNWGT.	19.77907
1	WGT.	20.96078
	UNWGT.	20.96078

- -

Variable .. VFSD

OH		
0	WGT.	70.77991
	UNWGT.	70.77991
1	WGT.	64.46078
	UNWGT.	64.46078

- -

Variable .. BVHI

OH		
0	WGT.	9.87647
	UNWGT.	9.87647
1	WGT.	9.18310
	UNWGT.	9.18310

- -

Variable .. BVCH4M

OH		
0	WGT.	1.17647
	UNWGT.	1.17647
1	WGT.	1.22535
	UNWGT.	1.22535

- -

Variable .. AGE

OH		
0	WGT.	73.86471
	UNWGT.	73.86471
1	WGT.	77.12676
	UNWGT.	77.12676 .

* * * * * * Analysis of Variance -- design 1 * * * * * *

Tests of Significance for VFCH4M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	39012.99	235	166.01		
REGRESSION	69881.10	4	17470.28	105.23	.000
OH	30.06	1	30.06	.18	.671
(Model)	69951.04	5	13990.21	84.27	.000
(Total)	108964.03	240	454.02		

R-Squared = .642
Adjusted R-Squared = .634

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE			
VARIABLE	VFSD	BVHI	BVCH4M	AGE
VFCH4M	-.903	-.323	.425	-.125

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
VFSD	.815
BVHI	.105
BVCH4M	.180
AGE	.016

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.642
OH	.001

- -

Estimates for VFCH4M adjusted for 4 covariates
--- Individual univariate .9500 confidence intervals

* * * * * * A n a l y s i s o f V a r i a n c e -- design 1 * * * * * *

Estimates for VFCH4M adjusted for 4 covariates (Cont.)
OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	-.40543118	.95280	-.42551	.67085	-2.28256	1.47169

- -

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH4M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
VFSD	-.81231	-.87054	.045	-18.147	.000
BVHI	7.19606	.54765	.920	7.818	.000
BVCH4M	6.48366	.44842	.855	7.581	.000
AGE	-.02749	-.01046	.110	-.249	.803

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
VFSD	-.901	-.724	.584
BVHI	5.383	9.009	.206
BVCH4M	4.799	8.169	.196
AGE	-.245	.190	.000

- -

Adjusted and Estimated Means
Variable .. VFCH4M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	19.779	19.964	19.779	.000	.000
2	20.961	20.775	20.961	.000	.000

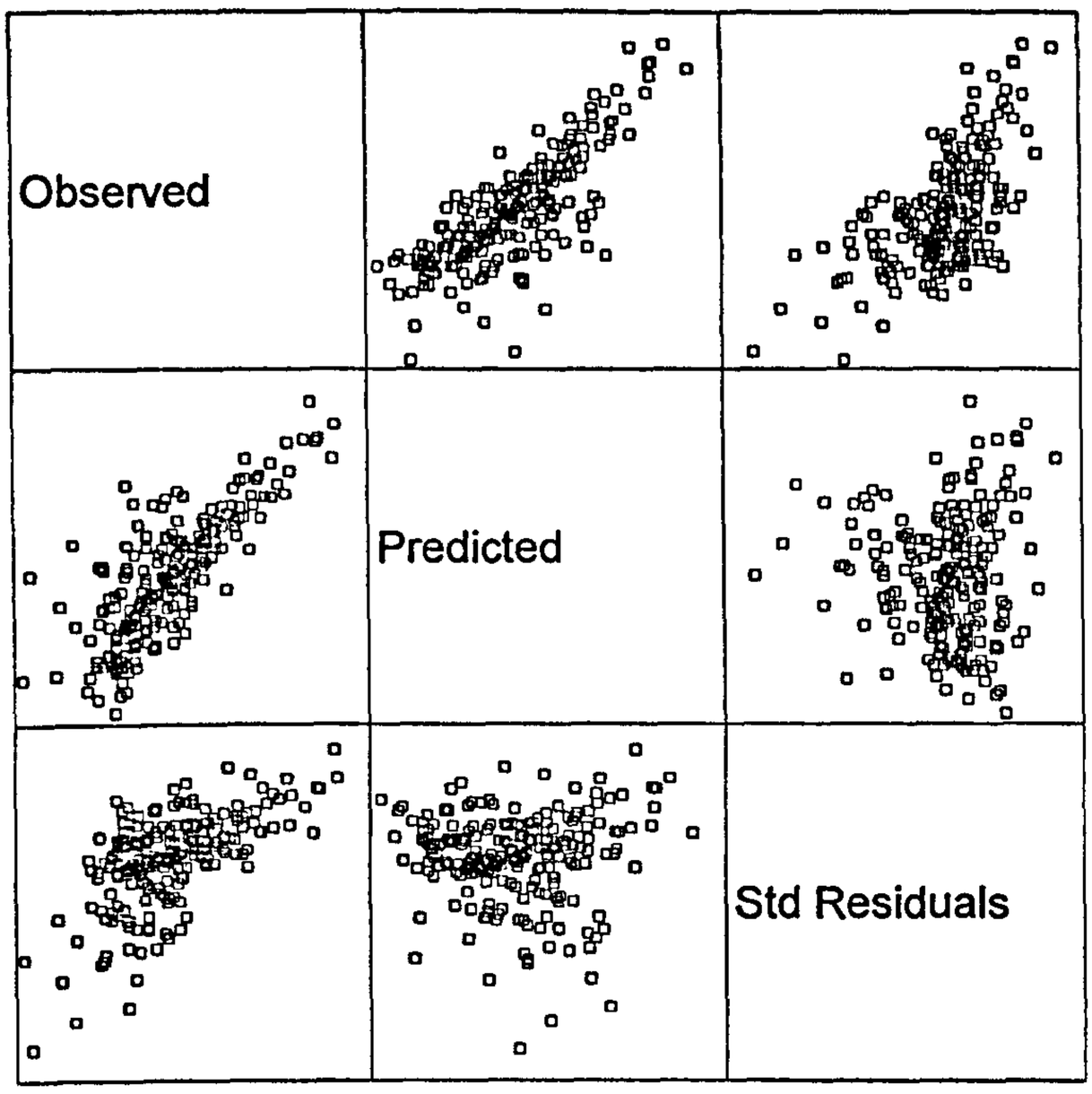
- -

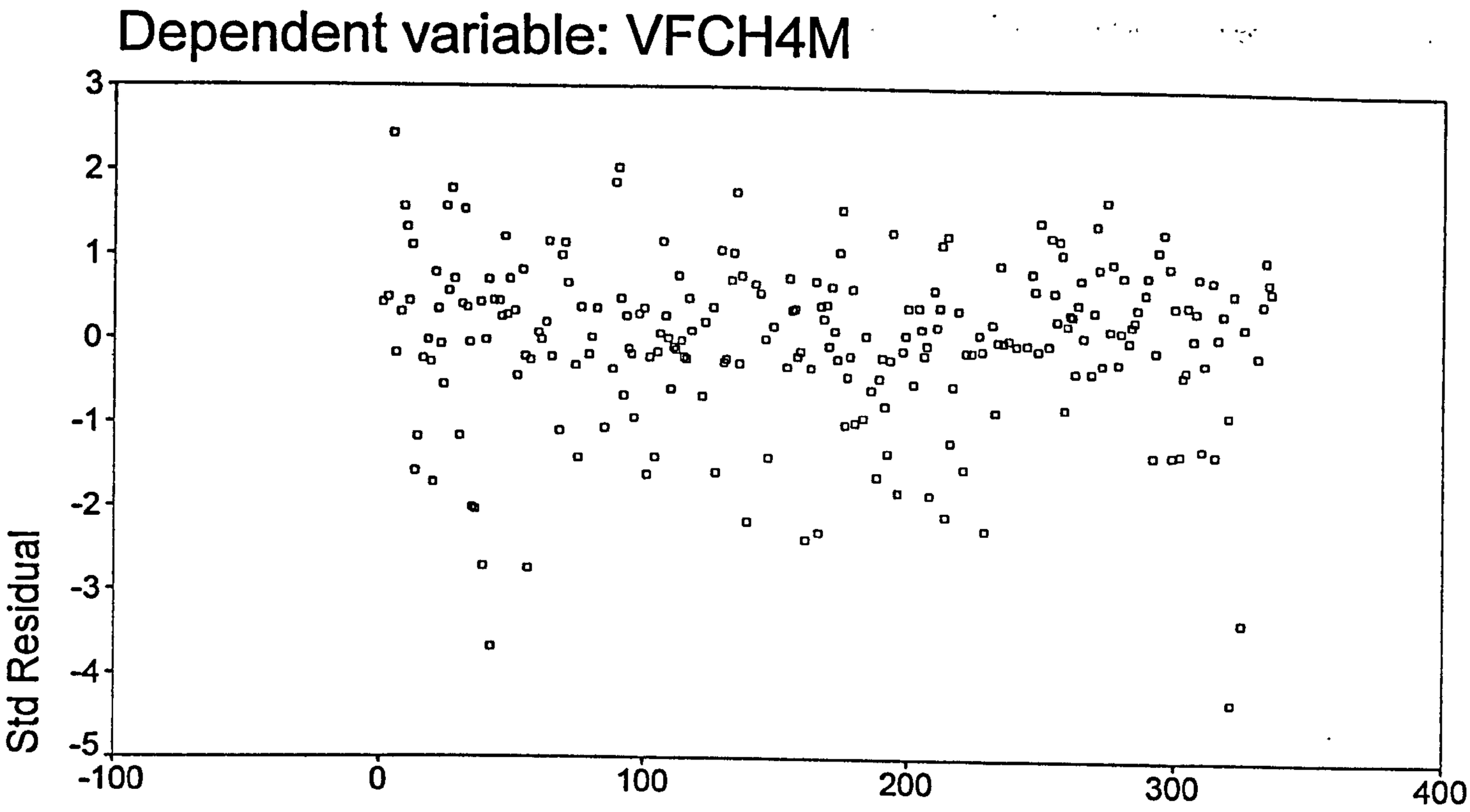
Hi-Res Chart # 61:Observed, predicted, residuals for vfch4m
Hi-Res Chart # 62:Case number vs. std. resid. for vfch4m
Hi-Res Chart # 63:Normal q-q plot of residuals of vfch4m
Hi-Res Chart # 64:Detrended normal q-q plot of residuals of vfch4m
****

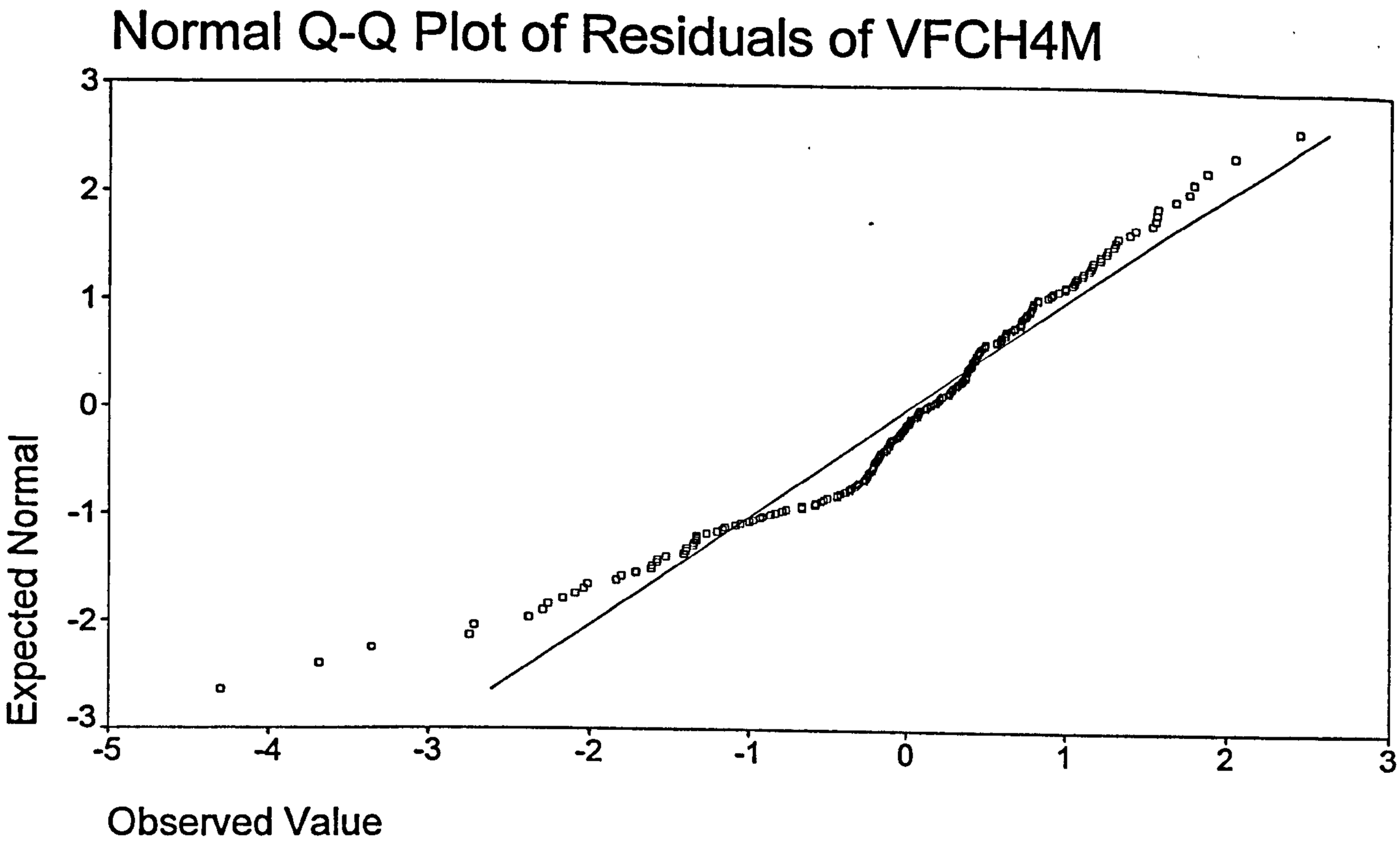
Combined Adjusted Means for OH
Variable .. VFCH4M

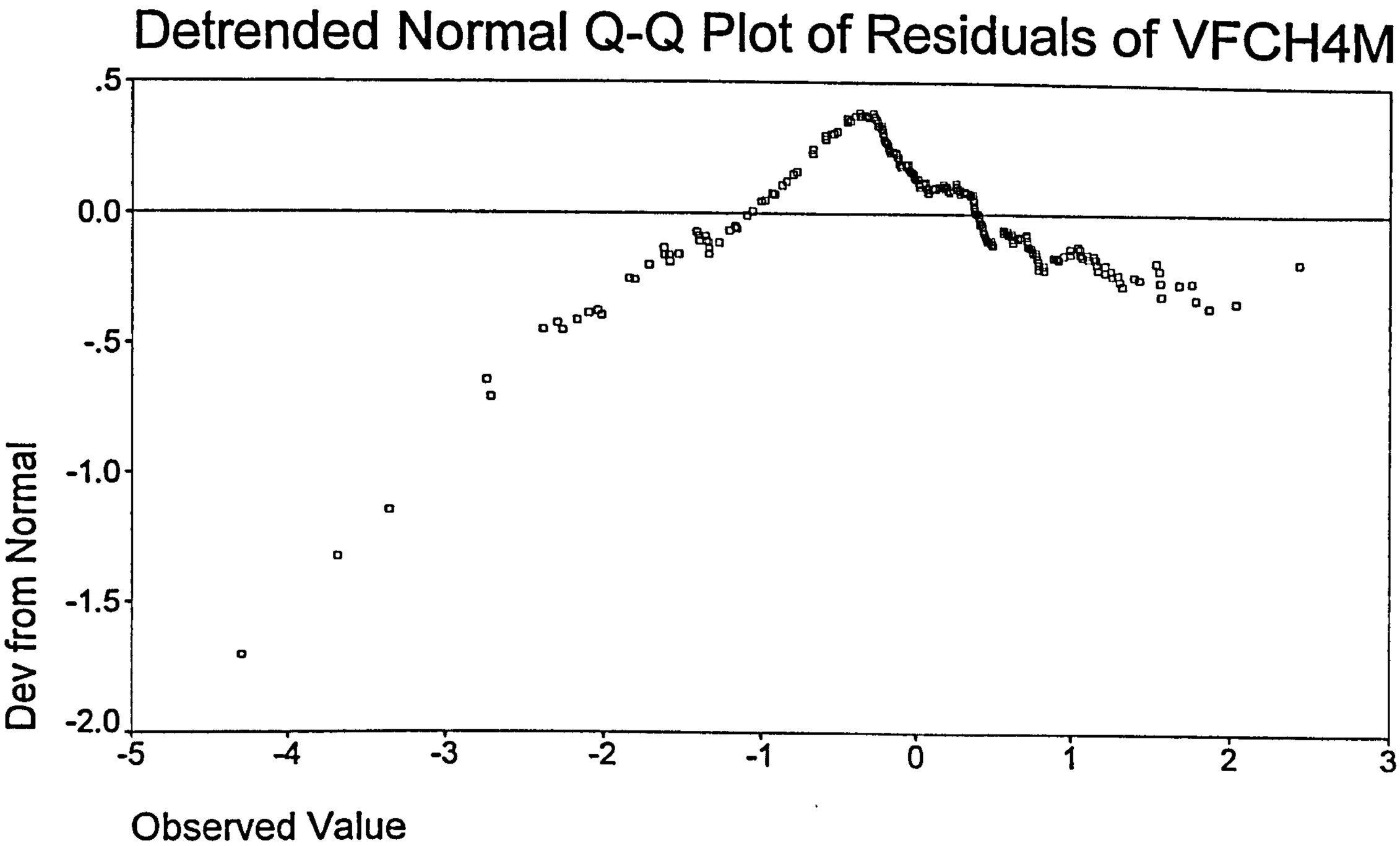
OH		
0	UNWGT.	19.96450
1	UNWGT.	20.77536

Dependent variable: VFCH4M




Dependent variable: VFCH4M
Std Residual
3
2
1
0
-1
-2
-3
-4
-5
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH4M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-5
-4
-3
-2
-1
0
1
2
3


Detrended Normal Q-Q Plot of Residuals of VFCH4M
Dev from Normal
.5
0.0
-.5
-1.0
-1.5
-2.0
-5
-4
-3
-2
-1
0
1
2
3
Observed Value

Appendix D4

Analysis of Covariance Models :

Determinants of Change in Visual Function at 12 Months

Adjusting for pre-operative factors (capacity for change)

- model 1
- model 2

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL 1[redacted].

CHANGE IN VF-14 SCORE AT 12 MONTHS AND PRE-OP BETTER EYE VISUAL ACUITY ADJUSTING FOR PRE-OP VF-14 SCORE.

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

261 cases accepted.
0 cases rejected because of out-of-range factor values.
17 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests
Variable .. VFCH12M

Cochrans C(64,4) = .30660, P = .296 (approx.)
Bartlett-Box F(3,40807) = 1.67464, P = .170

- -

Combined Observed Means for OH
Variable .. VFCH12M

OH		
0	WGT.	24.17131
	UNWGT.	26.08296
1	WGT.	20.07914
	UNWGT.	23.07568

- -

Variable .. VFSD

OH		
0	WGT.	69.59420
	UNWGT.	68.19316
1	WGT.	65.53335
	UNWGT.	62.75173

- -

Variable .. BVHI

OH		
0	WGT.	9.90556
	UNWGT.	9.86465
1	WGT.	9.29630
	UNWGT.	9.14430

- -

Variable .. AGE

OH		
0	WGT.	74.07222
	UNWGT.	74.21043
1	WGT.	77.07407
	UNWGT.	76.93888

- -

Combined Observed Means for E212M
Variable .. VFCH12M

E212M		
0	WGT.	19.36727
	UNWGT.	19.03084
1	WGT.	31.19276
	UNWGT.	30.12780

- -

Variable .. VFSD

E212M		
0	WGT.	70.79410
	UNWGT.	70.04340
1	WGT.	62.56199
	UNWGT.	60.90150

- -

Variable .. BVHI

```
          E212M
              0          WGT.      9.78689
                        UNWGT.     9.69892
              1          WGT.      9.55128
                        UNWGT.     9.31003
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
Variable .. AGE
          E212M
              0          WGT.     74.96721
                        UNWGT.    75.47669
              1          WGT.     75.08974
                        UNWGT.    75.67261
```

* * * * * * Analysis of Variance -- design 1 * * * * * *

Tests of Significance for VFCH12M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	39401.01	254	155.12		
REGRESSION	67212.71	3	22404.24	144.43	.000
OH	1280.19	1	1280.19	8.25	.004
E212M	834.46	1	834.46	5.38	.021
OH BY E212M	36.26	1	36.26	.23	.629
(Model)	75258.77	6	12543.13	80.86	.000
(Total)	114659.77	260	441.00		

R-Squared = .656
Adjusted R-Squared = .648

- -

Correlations between Covariates and Predicted Dependent Variable

COVARIATE

VARIABLE	VFSD	BVHI	AGE
VFCH12M	-.959	-.374	-.145

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
VFSD	.920
BVHI	.140
AGE	.021

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.630
OH	.031
E212M	.021
OH BY E212M	.001

- -

Estimates for VFCH12M adjusted for 3 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
2	2.87611467	1.00117	2.87277	.00441	.90447	4.84776

E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
3	-2.3056840	.99411	-2.31935	.02117	-4.26343	-.34794

OH BY E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95% CL-	Upper
4	-.47503566	.98255	-.48347	.62918	-2.41002	1.45995

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH12M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
VFSD	-.78576	-.84062	.043	-18.423	.000
BVHI	1.74340	.13436	.608	2.867	.004
AGE	-.10073	-.03872	.102	-.983	.327

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
VFSD	-.870	-.702	.572
BVHI	.546	2.941	.031
AGE	-.303	.101	.004

- -

Adjusted and Estimated Means
Variable .. VFCH12M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	20.150	24.675	20.150	.000	.000
2	32.016	30.236	32.016	.000	.000
3	17.911	19.873	17.911	.000	.000
4	28.240	23.534	28.240	.000	.000

Hi-Res Chart # 77:Observed, predicted, residuals for vfch12m
Hi-Res Chart # 78:Case number vs. std. resid. for vfch12m
Hi-Res Chart # 79:Normal q-q plot of residuals of vfch12m
Hi-Res Chart # 80:Detrended normal q-q plot of residuals of vfch12m

****

Combined Adjusted Means for OH
Variable .. VFCH12M

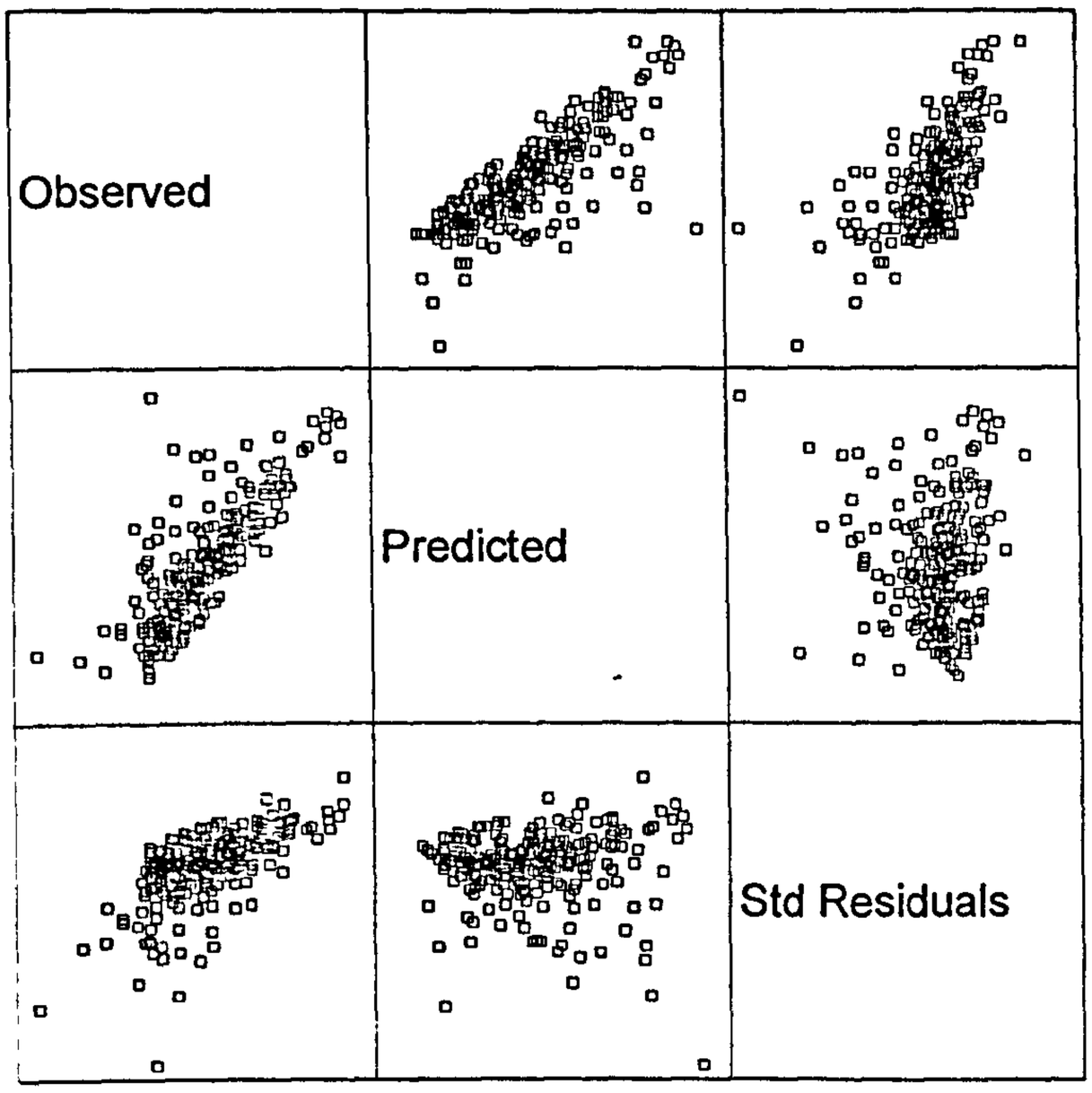
OH		
0	UNWGT.	27.45544
1	UNWGT.	21.70321

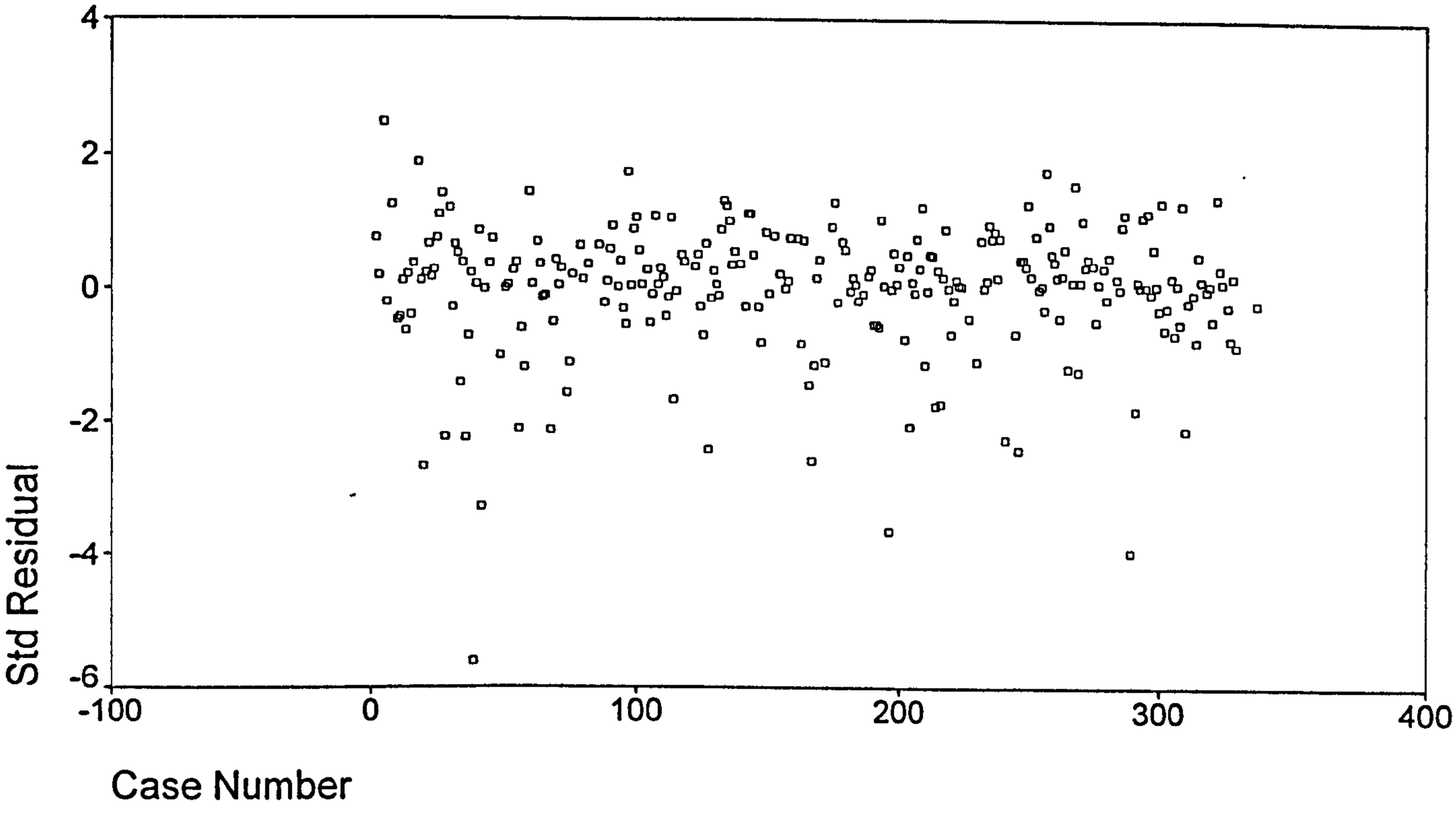
- -

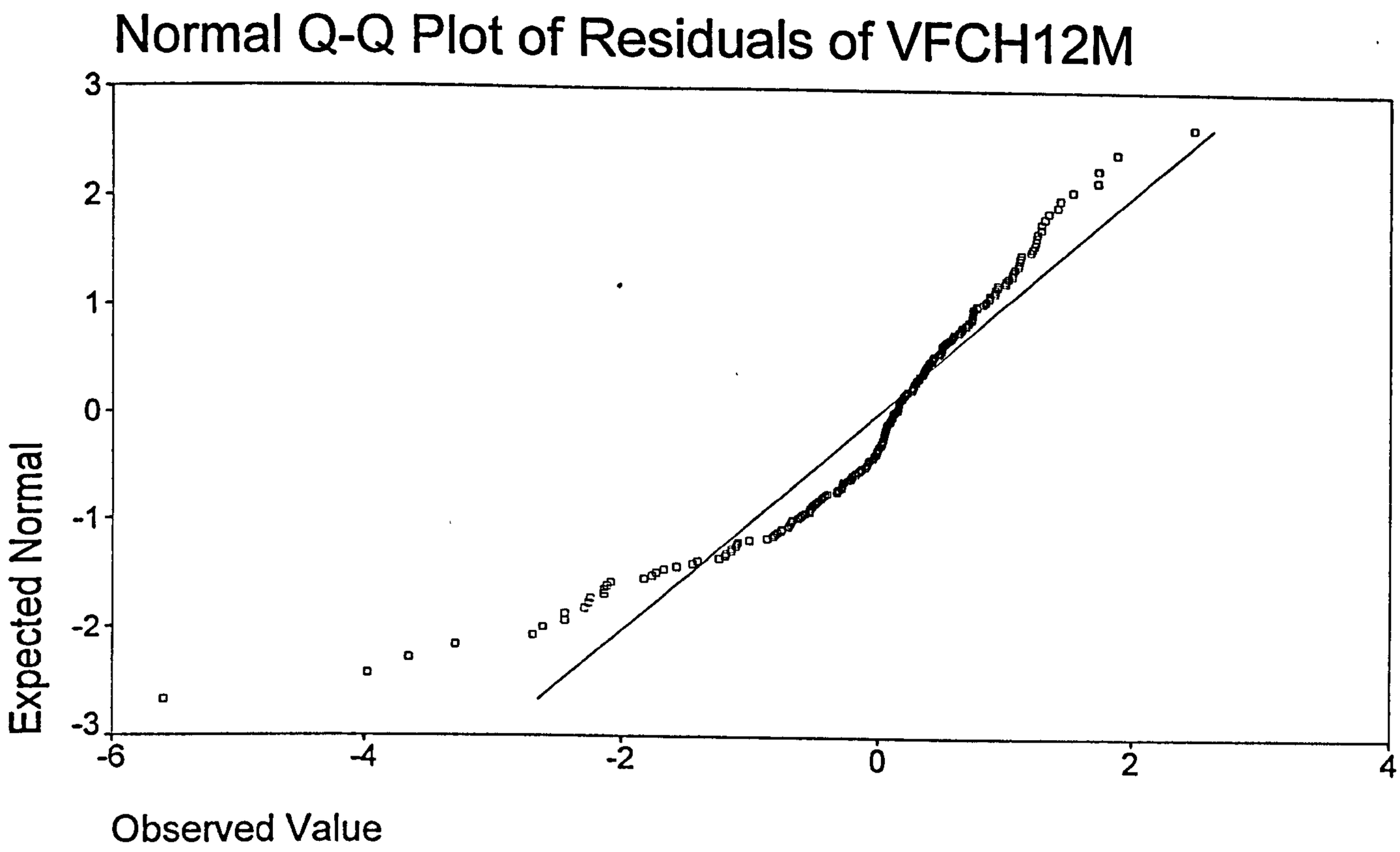
Combined Adjusted Means for E212M
Variable .. VFCH12M

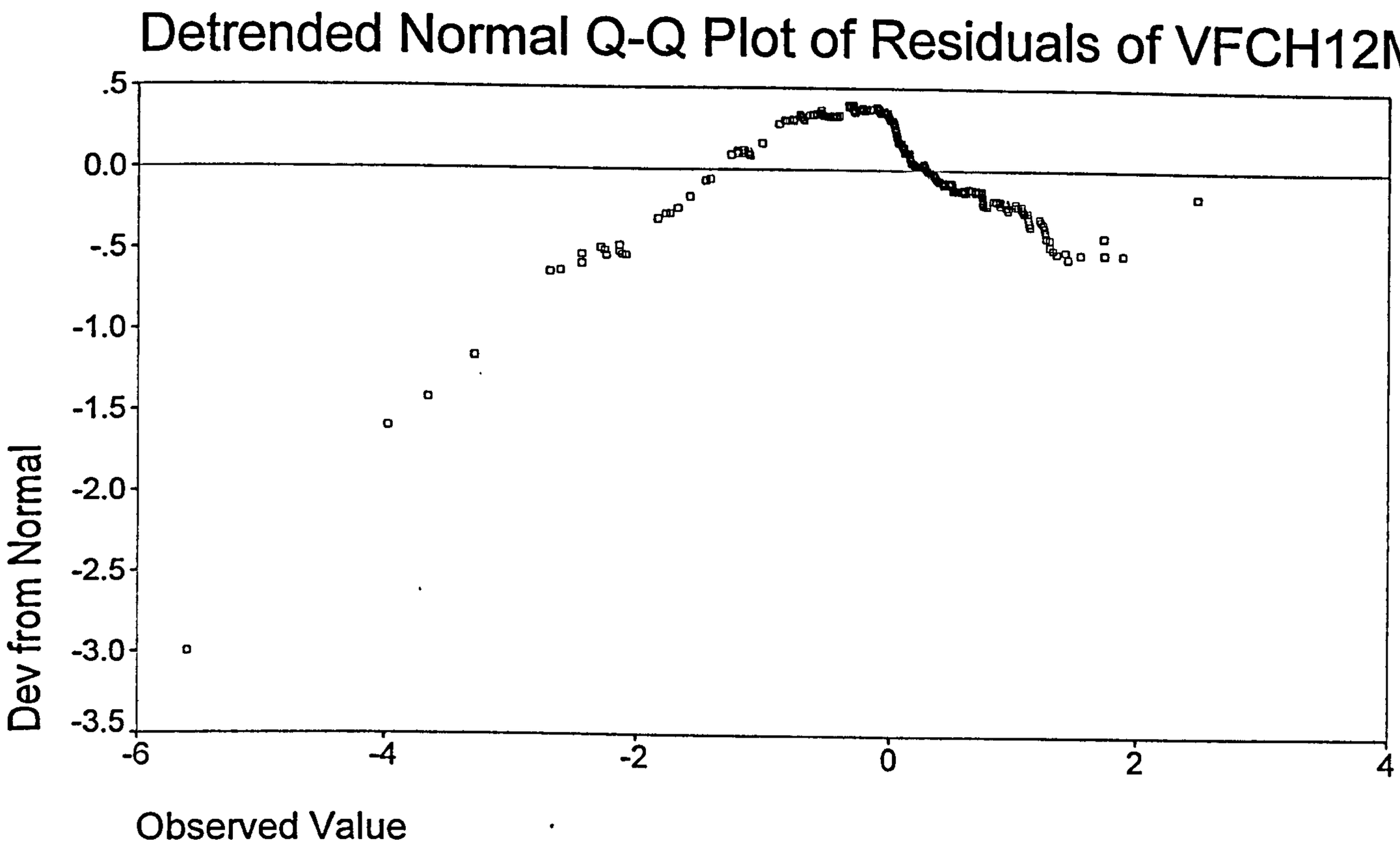
E212M		
0	UNWGT.	22.27364
1	UNWGT.	26.88501

Dependent variable: VFCH12M




Dependent variable: VFCH12M
4
2
0
-2
-4
-6
Std Residual
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH12M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-6
-4
-2
0
2
4


Detrended Normal Q-Q Plot of Residuals of VFCH12M
.5
0.0
-.5
-1.0
-1.5
-2.0
-2.5
-3.0
-3.5
Dev from Normal
-6
-4
-2
0
2
4
Observed Value

VFFU-3R.SAV ANALYSIS OF COVARIANCE MODEL 2.

CHANGE IN VF-14 SCORE AT 12 MONTHS AND CHANGE IN BETTER EYE VISUAL ACUITY AT 12 MONTHS ADJUSTING FOR PRE-OP VF-14 SCORE AND PRE-OP BETTER EYE VISUAL ACUITY.

* * * * * * A n a l y s i s o f V a r i a n c e * * * * * *

210 cases accepted.
0 cases rejected because of out-of-range factor values.
68 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.

- -

Univariate Homogeneity of Variance Tests

Variable .. VFCH12M

Cochrans C(52,4) = .31780, P = .242 (approx.)
Bartlett-Box F(3,26456) = 2.24987, P = .081

- -

Combined Observed Means for OH
Variable .. VFCH12M

OH		
0	WGT.	24.52758
	UNWGT.	26.36946
1	WGT.	18.56333
	UNWGT.	21.37541

- -

Variable .. VFSD

OH		
0	WGT.	69.33161
	UNWGT.	68.02941
1	WGT.	68.46519
	UNWGT.	65.72503

- -

Variable .. BVHI

OH		
0	WGT.	9.93151
	UNWGT.	9.87776
1	WGT.	9.43750
	UNWGT.	9.17714

- -

Variable .. BVCH12M

OH		
0	WGT.	1.26027
	UNWGT.	1.34736
1	WGT.	1.20313
	UNWGT.	1.33571

- -

Variable .. AGE

OH		
0	WGT.	74.01370
	UNWGT.	74.26783
1	WGT.	76.73438
	UNWGT.	77.08714

```
Combined Observed Means for E212M
Variable .. VFCH12M
        E212M
            0          WGT.     19.27357
                      UNWGT.     18.57162
            1          WGT.     30.72802
                      UNWGT.     29.17326

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
Variable .. VFSD
        E212M
            0          WGT.     71.51616
                      UNWGT.     71.29334
            1          WGT.     63.35414
                      UNWGT.     62.46110

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
Variable .. BVHI
        E212M
            0          WGT.      9.90476
                      UNWGT.      9.84062
            1          WGT.      9.49206
                      UNWGT.      9.21429

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
Variable .. BVCH12M
        E212M
            0          WGT.      1.08844
                      UNWGT.      1.09124
            1          WGT.      1.60317
                      UNWGT.      1.59184

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -
Variable .. AGE
        E212M
            0          WGT.     74.50340
                      UNWGT.     74.97742
            1          WGT.     75.63492
                      UNWGT.     76.37755
```

* * * * * * Analysis of Variance -- design 1 * * * * * *

Tests of Significance for VFCH12M using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN+RESIDUAL	18410.48	202	91.14		
REGRESSION	70812.56	4	17703.14	194.24	.000
OH	112.71	1	112.71	1.24	.267
E212M	465.26	1	465.26	5.10	.025
OH BY E212M	36.25	1	36.25	.40	.529
(Model)	77575.93	7	11082.28	121.59	.000
(Total)	95986.41	209	459.27		

R-Squared = .808
Adjusted R-Squared = .802

- -

Correlations between Covariates and Predicted Dependent Variable

	COVARIATE			
VARIABLE	VFSD	BVHI	BVCH12M	AGE
VFCH12M	-.892	-.367	.549	-.149

- -

Squared Correlations between Covariates and Predicted Dependent Variable

VARIABLE	AVER. R-SQ
VFSD	.796
BVHI	.135
BVCH12M	.301
AGE	.022

- -

Effect Size Measures

Source of Variation	Partial ETA Sqd
Regression	.794
OH	.006
E212M	.025
OH BY E212M	.002

Estimates for VFCH12M adjusted for 4 covariates
--- Individual univariate .9500 confidence intervals

OH

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
2	.964626701	.86742	1.11207	.26743	-.74572	2.67498

E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
3	-1.9208918	.85019	-2.25938	.02493	-3.59727	-.24452

OH BY E212M

Parameter	Coeff.	Std. Err.	t-Value	Sig. t	Lower -95%	CL- Upper
4	.530854593	.84171	.63069	.52896	-1.12881	2.19052

Regression analysis for WITHIN+RESIDUAL error term
--- Individual Univariate .9500 confidence intervals
Dependent variable .. VFCH12M

COVARIATE	B	Beta	Std. Err.	t-Value	Sig. of t
VFSD	-.84834	-.88131	.037	-22.945	.000
BVHI	7.36801	.53598	.736	10.006	.000
BVCH12M	7.52624	.52362	.662	11.365	.000
AGE	.08162	.03081	.089	.921	.358

COVARIATE	Lower -95% CL-	Upper	ETA Sq.
VFSD	-.921	-.775	.723
BVHI	5.916	8.820	.331
BVCH12M	6.220	8.832	.390
AGE	-.093	.256	.004

- -

Adjusted and Estimated Means
Variable .. VFCH12M

CELL	Obs. Mean	Adj. Mean	Est. Mean	Raw Resid.	Std. Resid.
1	20.767	23.447	20.767	.000	.000
2	31.972	26.227	31.972	.000	.000
3	16.376	20.456	16.376	.000	.000
4	26.375	25.360	26.375	.000	.000

Hi-Res Chart # 81:Observed, predicted, residuals for vfch12m
Hi-Res Chart # 82:Case number vs. std. resid. for vfch12m
Hi-Res Chart # 83:Normal q-q plot of residuals of vfch12m
Hi-Res Chart # 84:Detrended normal q-q plot of residuals of vfch12m

****

Combined Adjusted Means for OH
Variable .. VFCH12M

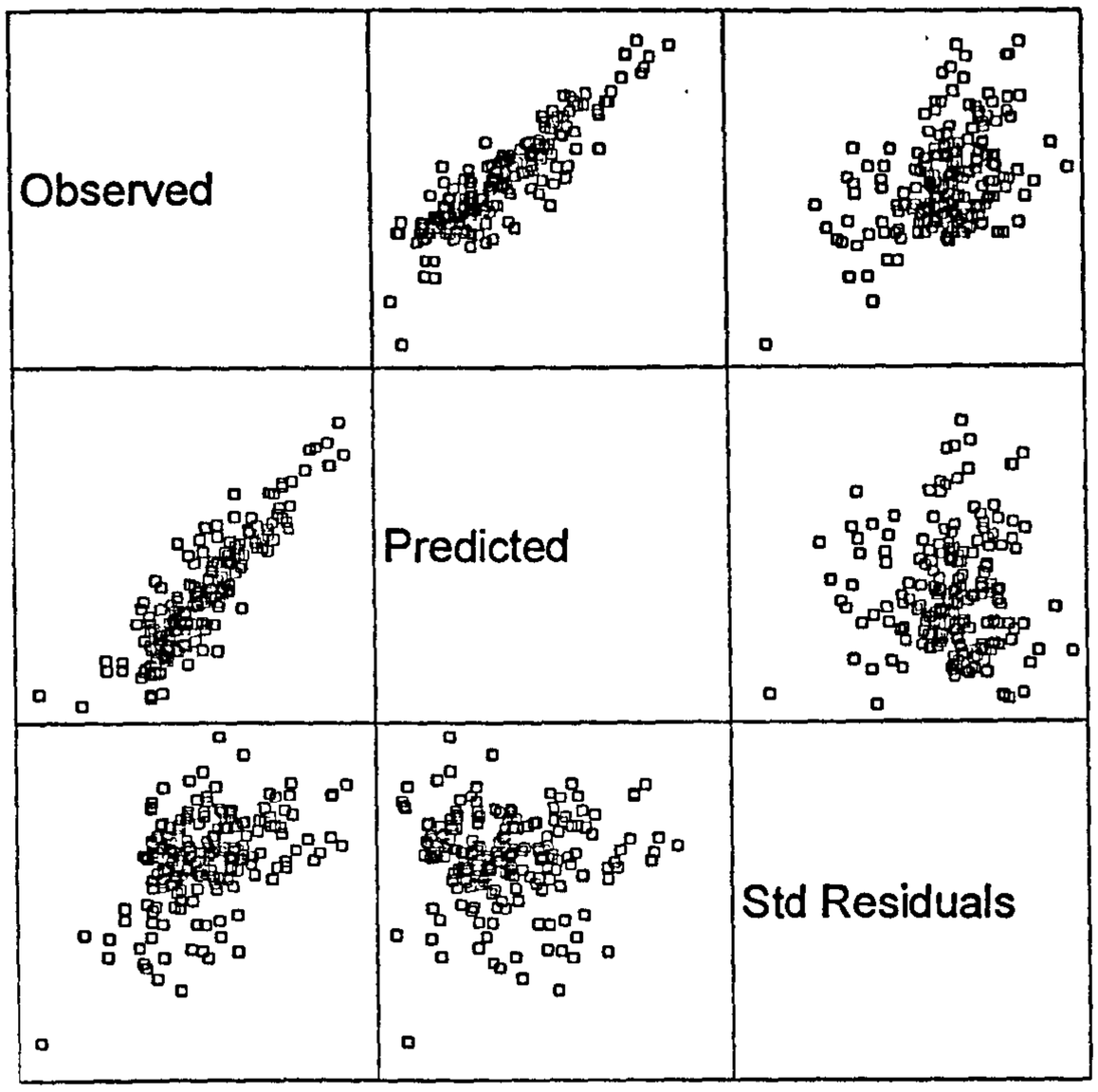
OH		
0	UNWGT.	24.83706
1	UNWGT.	22.90781

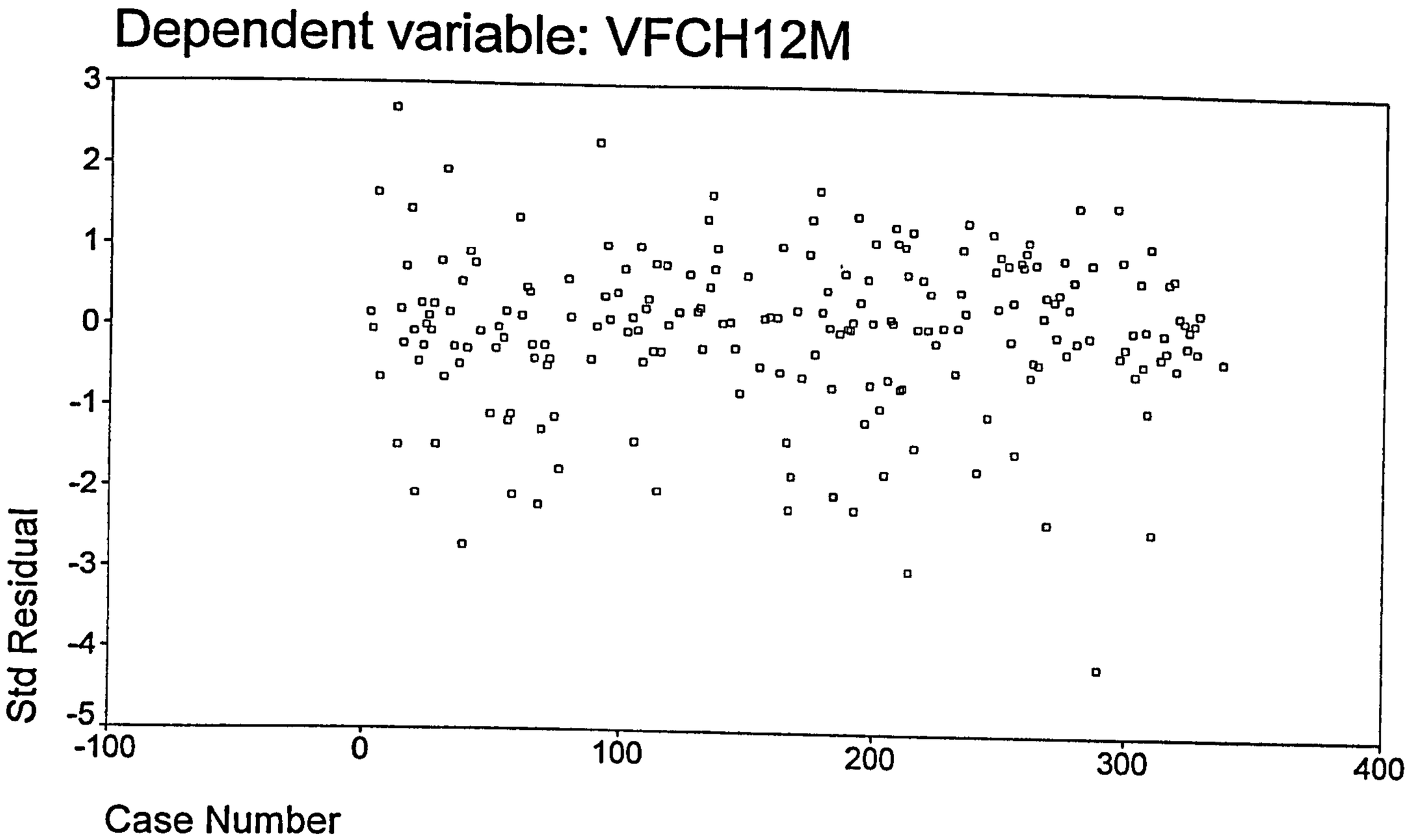
- -

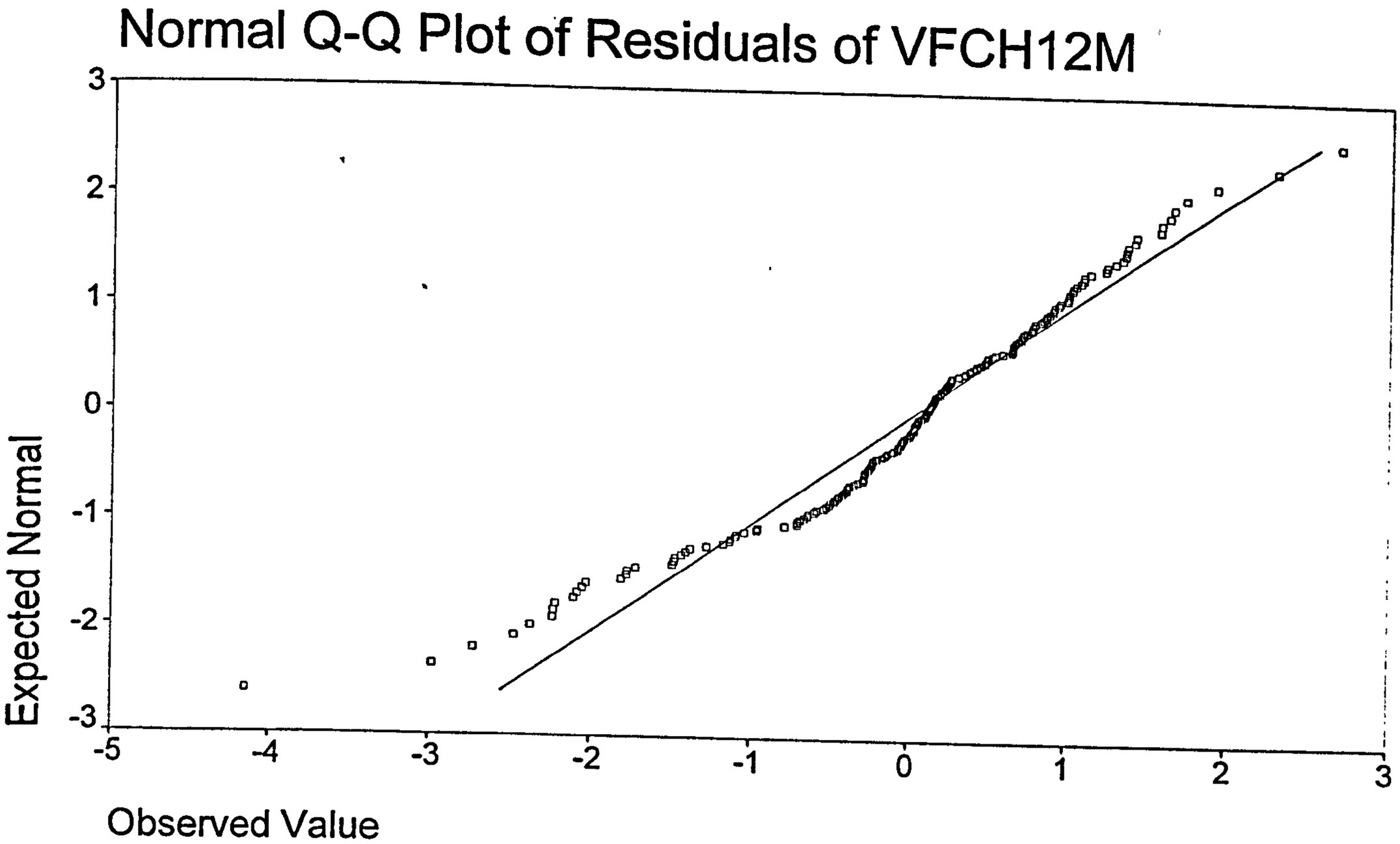
Combined Adjusted Means for E212M
Variable .. VFCH12M

E212M		
0	UNWGT.	21.95155
1	UNWGT.	25.79333

Dependent variable: VFCH12M




Dependent variable: VFCH12M
Std Residual
3
2
1
0
-1
-2
-3
-4
-5
-100
0
100
200
300
400
Case Number


Normal Q-Q Plot of Residuals of VFCH12M
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
-5
-4
-3
-2
-1
0
1
2
3